

UNIVERSIDAD COMPLUTENSE DE MADRID
FACULTAD DE MEDICINA
Departamento de Radiología y Medicina Física



**RADIOLOGÍA DIGITAL Y TÉCNICAS GUIADAS POR
FLUOROSCOPIA: IMPACTOS EN LA DOSIS DE RADIACIÓN
A LOS PACIENTES**

**MEMORIA PARA OPTAR AL GRADO DE DOCTOR
PRESENTADA POR**

José Miguel Fernández Soto

Bajo la dirección de los doctores

Eliseo Vañó Carruana
Eduardo Guibelalde del Castillo

Madrid, 2013

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Universidad Complutense de Madrid

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**Radiología digital y técnicas guiadas
por fluoroscopia. Impacto en las dosis
de radiación a los pacientes**

Memoria para optar al grado de doctor presentada por

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Tesis Doctoral en Formato de Publicaciones

Esta tesis doctoral se presenta en *formato publicaciones*, de acuerdo con el apartado 4.4 del acuerdo del Consejo de Gobierno de fecha 14 de octubre de 2008, en el que se aprueba la normativa de Desarrollo del Régimen relativo a la elaboración, tribunal, defensa y evaluación de la Tesis Doctoral del Real Decreto 1393/2007, de 29 octubre (BOE de 30 de octubre), por el que se establece la ordenación de las enseñanzas universitarias oficiales de la Universidad Complutense de Madrid. Dichas publicaciones recogen todos los resultados que han sido obtenidos en los diferentes trabajos de investigación desarrollados con el fin de alcanzar el objetivo fijado para la realización de la tesis.

A continuación se detallan los artículos que integran la tesis agrupados en dos bloques, teniendo en cuenta sus diferentes contenidos temáticos: radiología digital de proyecciones y procedimientos guiados por fluoroscopia.

Publicaciones incluidas en esta tesis

I.- Vaño E, **Fernández JM**, Ten JI, Prieto C, González L, Rodríguez R, de las Heras H. *Transition from screen-film to digital radiography: evolution of patient radiation doses at projection radiography*. Radiology 2007;243(2):461-6.

II.- **Fernandez JM**, Ordiales JM, Guibelalde E, Prieto C, Vano E. *Physical image quality comparison of four types of digital detector for chest radiology*. Radiat Prot Dosimetry 2008;129(1-3):140-3.

III.- Vano E, Martinez D, **Fernandez JM**, Ordiales JM, Prieto C, Floriano A, Ten JI. *Paediatric entrance doses from exposure index in computed radiography*. Phys Med Biol 2008;53(12):3365-80.

IV.- Prieto C, Vano E, Ten JI, **Fernandez JM**, Iñiguez AI, Arevalo N, Litcheva A, Crespo E, Floriano A, Martinez D. *Image retake analysis in digital radiography using DICOM header information*. J Digit Imaging 2009;22(4):393-9.

V.- Vano E, Ten JI, **Fernandez JM**, Prieto C, Ordiales JM, Martinez D. *Quality control and patient dosimetry in digital radiology. On line system: new features and transportability*. Radiat Prot Dosimetry 2008;129(1-3):144-6.

VI.- Vano E, Gonzalez L, Ten JI, **Fernandez JM**, Guibelalde E, Macaya C. *Skin dose and dose-area product values for interventional cardiology procedures*. Br J Radiol 2001;74(877):48-55.

VII.- Prieto C, Vano E, **Fernandez JM**, Martinez D, Sanchez R. *Increases in patient doses need to be avoided when upgrading interventional cardiology systems to flat detectors*. Radiat Prot Dosimetry 2011;147(1-2):83-5.

VIII.- Ten JI, **Fernandez JM**, Vaño E. *Automatic management system for dose parameters in interventional radiology and cardiology*. Radiat Prot Dosimetry 2011;147(1-2):325-8.

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Abreviaturas

AAPM	Asociación Americana de Físicos en Medicina
ACTP	Angioplastia Coronaria Transluminal Percutánea
AP	Antero-posterior
CI	Cardiología Intervencionista
COR	Coronariografía
CR	Radiología Computarizada
DI	Diagnóstico por Imagen
DICOM	Imagen Digital y Comunicación en Medicina
DIMOND	Imagen Digital: Medidas para Optimizar el Contenido en Información Radiológica y la Dosis
DOLIR	Dosis en Tiempo Real para Radiología Intervencionista
DOSE SR	Informe de Dosis Estructurado
DR	Radiología Digital
EC	Comisión Europea
EL	Nivel de Exposición
ESAK	Kerma en Aire en la Superficie de Entrada al Paciente
ESD	Dosis en la Superficie de Entrada al Paciente
EURATOM	Comunidad Europea de Energía Atómica
FP	Panel Plano
HCSC	Hospital Clínico San Carlos
ICRP	Comisión Internacional de Protección Radiológica
IEC	Comité Electrotécnico Internacional
IQFi	Inverso de la Figura de Mérito de Calidad de Imagen
MDP	Máxima dosis en piel
MPPS	Etapas Realizadas del Procedimiento por Modalidad
MUSICA	Amplificación del Contraste de la Imagen en Múltiples Escalas
NRDs	Niveles de Referencia Diagnósticos
NRPB	Organismo de Protección Radiológica Nacional del Reino Unido

PA	Postero-anterior
PACS	Sistema de Comunicación y Almacenamiento de Imágenes
PDA	Producto Dosis por Área
PDO	Organizador de Datos de Paciente
PMMA	Poli Metil Metacrilato
POP3	Protocolo de Oficina de Correo Electrónico
PSP	Fósforo Fotoestimulable
QCONLINE	Sistema de Control de Calidad y Dosis en Tiempo Real
RI	Radiología Intervencionista
RIS	Sistema de Información Radiológica
SAL	Nivel Medio de Señal
SCP	Proveedor de Servicio
SQL	Lenguaje Estándar de Consulta
SENTINEL	Eficacia y Seguridad para Nuevas Técnicas de Imagen usando Nuevo Equipamiento para Apoyar la Legislación Europea
SFM	Servicio de Física Médica

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1.- Introducción

Este trabajo se ha desarrollado en el Hospital Clínico San Carlos (HCSC), en los Servicios de Diagnóstico por Imagen y de Cardiología Intervencionista (CI). El Servicio de Diagnóstico por Imagen fue completamente reformado en el año 1999, incorporando a partir de ese momento los diferentes avances tecnológicos tanto en modalidades digitales (primeros sistemas de radiología computarizada (CR) y primeros equipos de radiología digital (DR) con panel plano (FP)), así como los sistemas de archivo y comunicación de imágenes (PACS) y de información radiológica (RIS). Esta actualización ha supuesto una estrecha colaboración del Servicio de Física Médica (SFM) en todos los aspectos relativos a dosimetría a pacientes, control de calidad de equipos y garantía de calidad de la Unidad Asistencial de Diagnóstico por Imagen en su conjunto, siendo el origen del interés en desarrollar en paralelo un sistema de gestión de dosis y calidad basado en las nuevas tecnologías implementadas. El Servicio de Cardiología Intervencionista también ha evolucionado actualizando sus modalidades a las últimas tecnologías en este periodo de tiempo, lo que también ha permitido evaluar su impacto.

El Hospital Clínico San Carlos propuso a la Comisión Internacional de Protección Radiológica (ICRP) el desarrollo de recomendaciones específicas sobre la gestión de las dosis a los pacientes en radiología digital, que dio como resultado la publicación número 93 de la Comisión [ICRP, 2004] en cuya redacción participó el doctorando.

1.1.- Radiología digital de proyecciones

La incorporación de los sistemas digitales a la radiología de proyecciones y su influencia en las dosis a los pacientes y la calidad de imagen se ha abordado con cinco trabajos que cubren otros tantos aspectos, que se han visto

influenciados por la constante evolución tecnológica y la aparición de nuevos sistemas digitales:

- evaluación retrospectiva de las dosis a pacientes adultos con un sistema de radiografía computarizada frente al sistema convencional existente previamente.
- evaluación física de la calidad de imagen proporcionada por diferentes sistemas digitales y su influencia en las dosis a los pacientes.
- dosis a pacientes pediátricos en un sistema de radiografía computarizada.
- análisis de la tasa de rechazo en radiografía digital a partir de la información contenida en las cabeceras DICOM.
- transportabilidad y nuevas funcionalidades de un sistema en tiempo real para control de calidad y dosimetría a pacientes en radiología digital.

A continuación se describen los fundamentos de cada uno de ellos:

1.1.1.- Transición de los sistemas de radiografía con cartulina-película a sistemas digitales.

El paso de los **sistemas convencionales** de cartulina y película a la radiología digital pueden suponer un incremento en las dosis de radiación a los pacientes [ICRP, 2004]. Una de las principales causas de este incremento es el amplio rango dinámico de los sistemas de imagen digitales, que permiten la sobreexposición sin que esto produzca ningún efecto adverso en la calidad de la imagen. Adicionalmente, la falta de formación específica en las nuevas técnicas digitales para el personal técnico y la ausencia de métodos bien establecidos para la auditoría de las dosis a los pacientes en sistemas digitales pueden complicar aún más el problema de la exposición del paciente a la radiación.

La Comisión Internacional de Protección Radiológica ha sido consciente de este riesgo y ha emitido diferentes recomendaciones específicas para el

manejo de las dosis a los pacientes en radiología digital [ICRP, 2004]. Estas recomendaciones incluyen la formación apropiada, particularmente en los aspectos de gestión de las dosis a los pacientes, revisión de los niveles de referencia de dosis, y realización de auditorías frecuentes de dosis a los pacientes. Adicionalmente la ICRP recomienda que la industria promueva herramientas para informar a los radiólogos, técnicos y radiofísicos sobre los parámetros de la exposición y las dosis resultantes.

En diferentes trabajos [Peters, 2002; Weatherburn, 2000] se ha puesto de manifiesto el riesgo de aumentar las dosis a los pacientes en la puesta en marcha de sistemas digitales debido a la configuración inicial de estos sistemas recomendadas por los fabricantes, y la posibilidad de reducción sustancial de los parámetros de exposición respecto a los valores iniciales al aplicar procedimientos de optimización. El **trabajo I** presenta una evaluación retrospectiva de las dosis a los pacientes en radiología de proyecciones después de la puesta en marcha de un sistema de radiografía computarizada en el que se describe cómo las dosis a los pacientes se incrementaron tras la implementación del sistema digital y cómo este incremento fue corregido en el primer año de funcionamiento del nuevo sistema, alcanzando incluso alguna reducción de dosis tras la puesta en marcha de las medidas correctoras.

1.1.2.- Comparación de la calidad de imagen proporcionada por diferentes tipos de detectores digitales en radiografía de tórax

En el **trabajo II** se aborda la comparación de cuatro sistemas de radiología digital dedicados a radiología de tórax en términos de calidad de imagen frente a la dosis a pacientes y se evalúa la posible optimización de la calidad de imagen. Antes de poner en marcha nuevos sistemas de radiología digital con sus posibles ventajas en la práctica clínica, es necesaria una comparación física que permita identificar las técnicas radiográficas en las que las posibles reducciones de dosis o mejoras en la calidad de imagen son esperables. En este trabajo se compara la calidad de imagen para exposiciones similares en un sistema de CR convencional, un sistema de CR con fósforo estructurado, y dos sistemas de radiología digital de panel plano. El sistema de CR con

fósforos estructurados y un digitalizador específicamente desarrollado para su lectura, permite la reducción de las dosis a los pacientes manteniendo suficiente calidad de imagen para el diagnóstico, o mejora la calidad de imagen en algunas exploraciones. En cualquier uso médico de las radiaciones ionizantes, obtener suficiente información diagnóstica debe ser la principal prioridad, pero prestando especial atención a las dosis de radiación a los pacientes debido a la probabilidad de producir efectos biológicos estocásticos. Por tanto la calidad de la imagen no debe ser mejor de la necesaria, sino la justa para el diagnóstico que se quiere obtener.

1.1.3.- Dosis a la entrada del paciente pediátrico a partir del índice de exposición en radiografía computarizada.

El **trabajo III** aborda la influencia de las modalidades digitales sobre la radiología pediátrica de proyecciones. Las dosis a los pacientes en pediatría son bajas (en general) pero los factores de riesgo para efectos probabilistas en niños son de tres a cuatro veces superiores a los de adultos [ICRP, 1991] y para algunos pacientes de corta edad los exámenes se repiten muchas veces en unas pocas semanas (como es el caso de los niños prematuros). Las publicaciones sobre dosis a pacientes pediátricos son todavía escasas, y aunque existen algunos trabajos [Azevedo, 2006; Mohamadain, 2004; Khoury, 2003; Compagnone, 2005; Montgomery, 2000; NRPB, 2002; Kiljunen, 2007], las muestras analizadas son normalmente pequeñas y los artículos sobre modalidades digitales son minoritarios. Los resultados dosimétricos en pediatría ayudarían a establecer niveles de referencia diagnósticos (locales o regionales).

La radiografía computarizada es todavía una de las modalidades digitales más comunes en muchos hospitales. Es especialmente común para pacientes pediátricos y para exploraciones radiológicas realizadas con equipos portátiles. Con la CR, no existe comunicación física entre el detector de imagen, constituido por el chasis y la placa de fósforo fotoestimulable (PSP) y el generador del equipo de rayos X. Por tanto no hay posibilidad de capturar los datos de la exposición del paciente y enviarlos al RIS o al PACS. Aunque

existen algunos generadores con interfaz propia de cada fabricante, no parece que se vaya a disponer de programas estandarizados para utilizar este tipo de interfaz en el futuro próximo.

Los principales fabricantes de sistemas de CR han tratado de compensar estas dificultades para auditar los parámetros de la exposición, introduciendo algunos indicadores de dosis relacionados con la cantidad de luz emitida por las placas de PSP durante el proceso de digitalización. En la actualidad, se está realizando un esfuerzo por parte de la Comisión Electrotécnica Internacional (IEC) para estandarizar estos índices de dosis, pero su aplicación práctica todavía requerirá algunos años más.

En el **trabajo III** se presentan resultados de kerma en aire en la superficie de entrada al paciente (ESAK), también expresado en la literatura como dosis en la superficie de entrada del paciente (ESD), a partir del nivel de exposición (EL), que es en sistemas de CR el parámetro indicador de la dosis relacionado con la cantidad de luz emitida por la placa de PSP durante el proceso de lectura. Estos resultados corresponden a 3501 exploraciones pediátricas realizadas durante 2 años en un hospital universitario. Este parámetro indicador de dosis es incluido en la cabecera DICOM de las imágenes y transferido automáticamente a una base de datos para su análisis.

1.1.4.- Análisis de tasa de rechazo de imágenes en radiografía digital usando la información contenida en las cabeceras DICOM.

El análisis de rechazo es descrito por el Grupo de Trabajo de Garantía de Calidad del Instituto Británico de Radiología como la evaluación crítica de las radiografías que se han usado como parte del servicio de imagen pero no juegan un papel útil en el proceso diagnóstico [BIR, 1998]. En radiología digital si consideramos imágenes en vez de radiografías, se refiere a aquellas imágenes rechazadas por no ser aceptables para el diagnóstico. La tasa de rechazo total es, por tanto, el número de imágenes eliminadas dividido por el número total de imágenes adquiridas durante un periodo de tiempo determinado. Es también posible calcular la tasa de repetición, definida como el

porcentaje de imágenes que han sido repetidas debido a errores o a una insuficiente calidad de imagen. La tasa de repetición no incluye aquellas imágenes que son diagnósticamente inaceptables pero por diferentes razones no son repetidas. Por otro lado, algunas de las imágenes que después son repetidas podrían tener suficiente calidad de imagen diagnóstica [Dunn, 1998], pero son eliminadas cuando la decisión de repetir o aceptar una imagen como diagnóstica es hecha exclusivamente por un técnico sin experiencia o no entrenado. Además en la mayoría de los países Europeos, los técnicos son entrenados para reconocer la anatomía pero no para reconocer la patología.

El análisis de la tasa de rechazo en radiología digital es un reto, y se han publicado muy pocos trabajos en este tema. El borrado de ficheros (imágenes) en un ordenador es mucho más fácil que arrojarlas a una papelera y más difícil de auditar. La realización de un control de tasa de rechazo manualmente presenta muchas dificultades con sistemas digitales, pero es aún más difícil de realizar de manera automática. En el **trabajo IV** se explora la posibilidad de monitorizar de manera automática las tasas de rechazo en departamentos de radiología digital.

La Directiva Europea de protección de la salud contra los peligros de la radiación ionizante en relación con la exposición médica [EC, 1997] pone gran énfasis en la justificación de las exploraciones radiográficas para asegurar que la dosis de radiación a los pacientes sea minimizada, y esto requiere gran consideración sobre eficacia diagnóstica de una imagen. Por tanto es importante realizar solamente las exploraciones clínicamente diagnósticas. El análisis de la tasa de repeticiones es un método para identificar fallos en la imagen, fuentes de error, y en general, prácticas inadecuadas. Es un aspecto clave en cualquier programa de garantía de calidad [Dunn, 1998; Boone, 2002; Hardy, 2001; Arvanitis, 1991; Gadeholt, 1992; Pitcher, 1992; Freedman, 1995], y una herramienta básica para evitar dosis innecesarias a pacientes en los departamentos de radiología [Honea, 2002; Nol, 2006], así como una forma de ahorrar tiempo en servicios que ya sufren una sustancial sobrecarga de trabajo, mejorando la eficiencia en el uso de equipos de rayos X y ahorrando espacio

en los sistemas de PACS. Todo esto podría contribuir a una mejor atención y cuidado a los pacientes.

Para asegurar un servicio de alta calidad, deben medirse indicadores dentro del entorno clínico, y una potencial herramienta de medida es el análisis de tasa de rechazo. El análisis de tasa de rechazo en un departamento moderno de imagen diagnóstica puede ser utilizado para identificar áreas donde es necesario mejorar la calidad del servicio y su efectividad.

La ICRP en su informe sobre manejo de las dosis a los pacientes en radiología digital [ICRP, 2004], destaca la importancia del análisis de repeticiones en los programas de garantía de calidad.

Ni los sistemas de CR ni los sistemas de PACS en sí mismos están diseñados en general para soportar el análisis de tasa de rechazo. En el **trabajo IV** se presenta una metodología que puede permitir la detección automática de rechazos potenciales en imagen digital usando la información contenida en la cabecera DICOM de las imágenes.

1.1.5.- Control de calidad y dosimetría a pacientes en radiología digital. Sistemas en tiempo real: nuevas funcionalidades y transportabilidad.

La cabecera DICOM de las imágenes archivadas (o de las series de fluoroscopia) contiene una información muy útil para la dosimetría de los pacientes y el control de calidad tanto para procedimientos radiológicos convencionales como para procedimientos guiados por fluoroscopia. Debería ser considerada una prioridad en el futuro, enriquecer y estandarizar esta información por la industria radiológica y hacerlo de tal manera que sea fácilmente disponible para los usuarios. La capacidad de transferir esa información a una base de datos para su posterior utilización debería ser también parte de este objetivo.

La ICRP en el documento sobre manejo de los pacientes en radiología digital [ICRP, 2004] destaca que la radiología digital representa uno de los más

grandes avances tecnológicos en imagen médica de la última década. Tiene el potencial de reducir la dosis a los pacientes, pero también el riesgo de incrementar el número de exposiciones y la dosis requerida para obtener imágenes de suficiente calidad. La experiencia ha mostrado que aunque muchos departamento radiológicos han hecho la transición al equipamiento digital, las dosis a los pacientes no han disminuido sino que se han incrementado significativamente [Vano, 2007]. La ICRP señala que la recogida de datos dosimétricos en tiempo real podría facilitar el manejo de las dosis y ayudar a prevenir dosis excesivas a los pacientes. La situación deseable en el futuro para las diferentes tecnologías digitales sería la extracción automática de la información de las cabeceras DICOM y su archivo en el RIS o en el PACS.

En un trabajo previo [Vano, 2005], se describió un sistema de auditoría en tiempo real basado en el procesamiento de la información desde las cabeceras DICOM. Este sistema no estaba restringido solamente a dosis a los pacientes; se disponía también de los datos de parámetros relevantes en la exposición y detalles del procedimiento de imagen así como un enlace con las propias imágenes. Los datos técnicos y demográficos fueron incluidos permitiendo que la calidad de la imagen también pudiera ser auditada como parte de un sistema de control de calidad completo sobre la base individual, si se requería, de mantener los parámetros dosimétricos y del procedimiento, relacionados con las imágenes clínicas.

En el **trabajo V**, se presentan nuevas funcionalidades adicionales al sistema antes descrito. Es posible activar indicadores de alarma que alerten del mal funcionamiento del sistema de rayos X o de modos de operación incorrectos, adicionalmente a los valores de dosis al paciente. El sistema se ha ampliado recientemente con la puesta en marcha de un nuevo módulo para analizar, recoger y procesar la información relevante transferida por el servicio DICOM MPPS, y se ha comprobado la transportabilidad del sistema a otros centros. Éstos resultados permiten complementar el trabajo que se está desarrollando en un grupo formado entre IEC y DICOM [IEC, 2007].

1.2.- Procedimientos guiados por fluoroscopia.

La realización de procedimientos guiados por fluoroscopia también se ha visto afectada por la introducción de sistemas de imagen digitales, si bien este cambio se ha desarrollado de una manera más gradual, iniciado con el paso de sistemas de adquisición de imagen de cine a registros digitales, y completado con la sustitución del intensificador de imagen por paneles planos dinámicos. Esta parte se ha abordado con tres trabajos que cubren los siguientes aspectos:

- Evaluación de dosis a pacientes en cardiología intervencionista previamente a la digitalización completa de los equipos, estableciendo los parámetros dosimétricos a ser monitorizados y proporcionando unos valores de referencia iniciales.
- La necesidad de evitar los incrementos en dosis a los pacientes cuando se actualizan los sistemas de cardiología intervencionista con detectores de panel plano.
- Utilidad de los sistemas de manejo automático de parámetros dosimétricos en radiología y cardiología intervencionistas.

A continuación se describen los aspectos más relevantes de cada uno de ellos:

1.2.1.- Valores de dosis en piel y producto dosis por área en procedimientos de cardiología intervencionista.

La radiología intervencionista (RI) y la cardiología intervencionista son las áreas donde se imparten unas dosis de radiación más altas a los pacientes. Los beneficios obtenidos compensan el riesgo radiológico, pero existe un riesgo significativo de inducir efectos deterministas, en forma de lesiones en la piel del paciente, entre otros riesgos [Wagner, 1998; Wagner, 1999; Patee, 1993; Cascade, 1987; Meier, 1997; Federman, 1994; Wagner, 1994; Martin, 1995; McParland, 1998; Betsou, 1998; Zorzetto, 1997]. El producto dosis por área (PDA) es una buena magnitud para estimar el riesgo de efectos probabilistas al paciente [Stern, 1995; LeHeron, 1992] y puede ser evaluado mediante el uso

de cámaras de transmisión o mediante procedimientos de cálculo, siendo preceptivo en la actualidad (en España y otros países de la Unión Europea) que los equipos para RI y CI incorporen equipos de medida o cálculo y registro de dosis a los pacientes, si bien esto es relativamente reciente y hace pocos años solamente algunos equipos incorporaban este tipo de dispositivos.

La ICRP recomienda [ICRP, 1996] el registro de los valores de PDA para el establecimiento de valores de referencia de dosis locales [Zorzetto, 1997; Karppinen, 1995; Pratt, 1993; Vano, 1995; Ten, 1998], pero esta magnitud no es un indicador adecuado para estimar el riesgo de efectos deterministas en procedimientos de RI o CI largos o con equipos de rayos X no optimizados, siendo conveniente la evaluación de la máxima dosis recibida en la piel.

La máxima dosis en la piel no es fácil de medir ya que en los procedimientos de CI y RI, el haz de rayos X penetra en el paciente por diferentes sitios, con diferentes ángulos y con un tamaño y forma del campo de radiación muy variable. Las estimaciones basadas en el rendimiento del tubo de rayos X, el potencial (kV) y la corriente (mA) ajustados, proporcionan normalmente resultados que pueden ser en ocasiones poco realistas, dadas la variaciones de área irradiada y de distancia entre el foco y la piel del paciente. Esta medida se puede realizar con dosímetros de termoluminiscencia correctamente posicionados en la piel del paciente, pero es difícil prever con exactitud la zona de la piel del paciente que va a ser más irradiada, por lo que este procedimiento es de difícil aplicación. Otra forma de evaluar este tipo de riesgos es mediante el uso de películas lentas [Geise, 1990; Fajardo, 1995; Vano, 1997] o de películas radiocrómicas de gran tamaño situadas a la entrada del haz de rayos X en la piel del paciente. Las zonas más irradiadas y el nivel de dosis alcanzado puede ser visualizado directamente en la imagen obtenida, que además proporciona información adicional sobre el uso de la colimación y los filtros semitransparentes, y puede permitir proponer medidas de optimización sobre el protocolo del procedimiento.

El **trabajo VI** presenta valores experimentales de PDA y de máxima dosis en la piel (MDP) del paciente, en los dos procedimientos más frecuentes de CI,

coronariografía (COR) y angioplastia coronaria transluminal percutánea (ACTP) mostrando las técnicas dosimétricas existentes y sus limitaciones antes de la utilización de sistemas completamente digitales equipados con detectores de panel plano. Los datos constatan la influencia del protocolo aplicado por el cardiólogo que realiza el procedimiento junto con la patología del paciente sobre los valores de PDA y MDP. A la vista de la variabilidad de estos datos, es necesario alertar a los especialistas médicos de la importancia de adoptar medidas conservadoras de protección radiológica, y alertar a los físicos médicos que el PDA y otras aproximaciones basadas en el rendimiento del equipo, no suelen ser suficientes para estimar la MDP en este tipo de procedimientos.

1.2.2.- Es necesario evitar el incremento en las dosis a los pacientes cuando se actualizan los sistemas de cardiología intervencionista con detectores de panel plano.

Los nuevos sistemas digitales presentan ventajas [Spahn, 2005] (ausencia de distorsión geométrica, excelente contraste, gran rango dinámico, alta sensibilidad a los rayos X y capacidad de procesamiento avanzada) con respecto a los sistemas convencionales. Estas ventajas deberían facilitar los procedimientos de CI y teóricamente dar la oportunidad de optimizar las técnicas en términos de dosis de radiación [Tsapaki, 2004].

Los procedimientos de CI complejos son procedimientos de alta dosis tanto para el paciente como para el personal de operación, produciendo, en algunas ocasiones, efectos deterministas (daños en la piel) debidos a las altas dosis de radiación impartidas en algunas regiones de la piel del paciente [ICRP, 2000; Koenig, 2001; Vano, 1998]. La angioplastia coronaria transluminal percutánea (ACTP) es uno de los procedimientos intervencionistas más frecuentes en cardiología y algunas veces requiere largos tiempos de fluoroscopia y gran número de imágenes de cine para evaluar y cuantificar la lesión del paciente y documentar el resultado del tratamiento. Por tanto, la estimación de dosis a los pacientes y su evolución en procedimientos intervencionistas es un aspecto clave para cualquier programa de garantía de calidad.

En el **trabajo VII** se analizan las dosis a los pacientes a lo largo de un periodo de 1 año durante el cual se actualizaron los sistemas de imagen de dos laboratorios de CI, de intensificador de imagen a panel plano.

1.2.3.- Sistemas de manejo automático de parámetros dosimétricos en radiología y cardiología intervencionistas.

La ICRP ha identificado a la RI y CI como prácticas que necesitan un programa de protección radiológico robusto [EC, 1997; ICRP, 2008; ICRP, 2007] y ha recomendado el uso de niveles de referencia diagnósticos (NRDs) en procedimientos guiados por fluoroscopia. La Directiva Europea 97/43/EURATOM y el borrador de las nuevas Normas Básicas de Seguridad Europeas requieren que las dosis a los pacientes sean medidas, registradas y transferidas a la historia clínica. Se han realizado muchos esfuerzos en la industria radiológica y en las organizaciones encargadas de los aspectos de normalización durante los últimos años para cumplir estos requerimientos.

Aparte de los requerimientos legales, los radiólogos, cardiólogos y físicos médicos, necesitan conocer los parámetros de exposición a la radiación y las dosis a los pacientes resultantes para ayudar en el proceso de optimización. Este conocimiento permite establecer comparaciones con los NRDs e iniciar acciones correctoras cuando, para algunos tipos de procedimientos, las dosis a los pacientes superan los NRDs.

Se han documentado daños por radiación en la piel de pacientes [ICRP, 2000; Koenig, 2001; Koenig, 2001b; Vano, 1998; Vano, 2001] en un número significativo de casos y es necesario considerar el seguimiento clínico de los pacientes que reciben altas dosis de radiación. Además, como la complejidad de algunos procedimientos intervencionistas y las terapias mínimamente invasivas están creciendo, también aumenta el porcentaje de pacientes que reciben altas dosis de radiación.

En muchos servicios de CI y RI, el número de laboratorios de cateterización y de procedimientos realizados diariamente puede ser bastante alto (3-6 laboratorios y 20-40 procedimientos al día). Parece conveniente por tanto desarrollar un sistema automático para recibir y procesar los principales parámetros radiográficos, geométricos y dosimétricos del paciente en tiempo real, para el seguimiento de los programas de calidad y de protección radiológica.

El **trabajo VIII** presenta el desarrollo de un sistema de gestión automática para analizar y archivar los principales parámetros del estudio y los valores de dosis al paciente en procedimientos de RI y CI en un gran hospital universitario así como ofrecer la experiencia a otras instituciones.

2.- Objetivos

El objetivo global del trabajo ha sido analizar el impacto en la dosis a los pacientes y en la optimización de la calidad de imagen que ha supuesto la incorporación de sistemas digitales en radiodiagnóstico y en los procedimientos intervencionistas guiados por fluoroscopia.

El objetivo global se ha abordado mediante aspectos específicos en cada uno de los artículos que componen este trabajo de la siguiente manera:

Con respecto a la radiografía de proyecciones se ha realizado:

- una evaluación retrospectiva de dosis a los pacientes después de la transición desde los sistemas de película cartulina a la CR.
- una evaluación de la calidad de la imagen obtenida con condiciones de exposición similares en varios sistemas digitales, para radiografía de tórax.
- una evaluación de las dosis en pediatría en radiología de proyecciones a partir del nivel de exposición proporcionado por el sistema de CR.
- una metodología para detectar de manera automática, potenciales repeticiones de imágenes en sistemas digitales.
- nuevas funcionalidades para un sistema de auditoría de parámetros técnicos y dosimétricos en tiempo real, en un departamento con radiología digital, usando la información contenida en las cabeceras DICOM de algunas modalidades.

Con respecto a los procedimientos guiados por fluoroscopia:

- Obtener valores de dosis en piel, producto dosis por área y otros parámetros operacionales en procedimientos de CI (ACTP y COR), establecer la relación entre estos parámetros e identificar las

herramientas dosimétricas utilizables, antes de la implantación de sistemas de imagen digitales.

- La evaluación de dosis a pacientes en dos laboratorios de CI durante el periodo de actualización de los sistemas de imagen, de intensificador a panel plano y seguimiento del impacto durante el primer año.
- Desarrollar e implantar un sistema de gestión automática, análisis y archivo de los principales parámetros de los estudios y las dosis a los pacientes en procedimientos guiados por fluoroscopia de CI y RI.

3.- Material y Método

Todos los trabajos se han desarrollado en el Hospital Clínico San Carlos que es un hospital universitario con aproximadamente 1000 camas y una población atendida del orden de 500.000 personas cuando se realizaron la mayor parte de estos trabajos, cuyo departamento de radiología comenzó su digitalización en 1999 y realiza del orden de 350.000 estudios anuales. El servicio de CI ha realizado durante estos últimos años, unos 4500 procedimientos anuales.

3.1.- Radiología digital de proyecciones.

3.1.1.- Transición de los sistemas de radiografía con cartulina-película a sistemas digitales.

El **trabajo I** fue realizado con los pacientes examinados entre 1999 y 2001 en 3 salas equipadas con generadores Philips Optimus 50 dedicadas a radiología general de proyecciones. Los equipos estaban conectados a un ordenador personal a través de un sistema de registro de datos de Philips llamado "Patient Data Organizer". Los sistemas disponían de control automático de exposición, ajustados por el servicio técnico del fabricante para sistemas de cartulina-película o sistemas equivalentes de CR de velocidad nominal 400, y sometidos a un control de calidad periódico por el Servicio de Física Médica del Hospital. Las capas hemirreductoras medidas a 80 kVp estuvieron entre 3,9 y 4,0 mm Al (valores típicos para estos equipos). Estas mismas salas, equipadas con otros sistemas de rayos X, fueron utilizadas entre 1997 y 1998 para radiología convencional con cartulina-película, también ajustadas a una velocidad de 400, lo que permitió realizar una de las primeras evaluaciones del impacto de la implantación de la tecnología digital.

Desde 1999, se utilizaron sistemas de CR AGFA ADC Compact, con placas de fósforo fotoestimulable AGFA MD10, MD30 y MD40. Las condiciones de exposición no cambiaron en función del modelo de placa de fósforo fotoestimulable utilizado, y además se simultaneó su uso.

Los sistemas disponían de programación anatómica definiendo para cada tipo de exploración radiográfica, los parámetros de exposición (kVp, tamaño de foco, cámara para el control automático de exposición y distancia foco-piel) ajustados de acuerdo a los criterios de calidad europeos para radiodiagnóstico [EC, 1996]. El técnico de imagen tiene la posibilidad de cambiar estos parámetros usando el modo manual en lugar del control automático de exposición, en función de las características de cada paciente o de sus propias preferencias.

Se elaboró un programa en Microsoft Visual Basic para realizar una monitorización en tiempo real, que proporcionaba los detalles de la técnica radiográfica, recuperando los mAs, el kVp, tamaño de campo y la distancia entre el foco y el detector para cada exposición. Con estos datos, se calculaba la dosis a la entrada del paciente (dosis absorbida en aire en la superficie del paciente, en el centro del área irradiada, incluyendo la retrodispersión del propio paciente) a partir de los rendimientos del tubo de rayos X. Estos rendimientos se medían periódicamente como parte del programa de control de calidad existente en el hospital. Para este cálculo se asume un espesor medio de paciente para cada tipo de exploración. El programa también realizaba una comparación en tiempo real, del valor medio de dosis calculadas para una muestra definida, con los valores locales de referencia, con objeto de auditar niveles de dosis a los pacientes y poder introducir medidas correctoras si fuera necesario [Vano, 2002].

Las dosis monitorizadas con el sistema descrito fueron obtenidas con unidades "bucky" de Philips en mesa o murales. En ambos casos, las distancias foco-detector fueron proporcionadas por un sensor unido a la posición del tubo de rayos X, junto con el resto de datos técnicos de la exposición. El factor de retrodispersión se asumió como 1,35 para todas las exploraciones, como se recomienda en el documento de criterios de calidad europeos [EC, 1996]. Las exploraciones realizadas sin "bucky" no fueron analizadas, porque la distancia foco-detector no estaba disponible en esos casos.

Hasta 2001, la puesta en marcha de los nuevos sistemas digitales instalados en 1999 en el HCSC fue realizada por el proveedor mediante unas pocas sesiones informativas. No se incluyó inicialmente un entrenamiento específico para optimizar las dosis a los pacientes o la calidad de imagen con los nuevos sistemas digitales. En 2001, el SFM del Hospital realizó un programa de formación específico para técnicos. Este programa tuvo una duración de 10 horas y se desarrolló a lo largo de una semana, y sus contenidos incluyeron conceptos de protección radiológica general, introducción a la imagen digital, radiografía con CR y paneles planos, recomendaciones de uso, y manejo de las dosis a pacientes en CR. Dado que las técnicas de exposición manual se utilizaban ocasionalmente, se puso especial atención en el impacto que podía tener sobre la dosis a los pacientes, cambiar los parámetros técnicos y los valores óptimos de kVp, mAs y distancia foco-piel para cada tipo de examen. Adicionalmente el programa desarrollado de monitorización de dosis en tiempo real fue utilizado como una herramienta rutinaria para auditar las dosis a los pacientes y quedó formalmente integrado en el programa de garantía de calidad del hospital.

Los radiólogos que trabajaban con las salas monitorizadas, evaluaron la calidad de la imagen anualmente como parte del programa de control y garantía de calidad, sobre muestras aleatorias y utilizando los criterios recomendados en las guías europeas [EC, 1996]. De acuerdo a los informes de control de calidad, las imágenes tuvieron suficiente calidad diagnóstica durante los años evaluados.

Con relación a los datos de dosis a los pacientes, el Comité de Ética aprobó el estudio de seguimiento de exposición a los pacientes (de forma anónima) y excluyó la necesidad de solicitar el consentimiento informado. En el periodo 1997-1999 con los sistemas de cartulina y película, los resultados de dosis a pacientes eran escasos, porque los datos de técnica radiográfica y las distancias eran recogidos manualmente y solamente los necesarios para el programa de control de calidad. En ese momento, la regulación nacional requería una muestra de 10 pacientes estándar por tipo de exploración y año, y

el tórax y la columna lumbar fueron elegidos como exploraciones diana para el control de calidad.

Los primeros sistemas de imagen digital fueron puestos en funcionamiento en el HCSC en 1999 y se abordó un amplio estudio para evaluar el impacto de la implantación de la tecnología digital para los procedimientos más relevantes con niveles de referencia diagnósticos publicados en las directrices europeas [EC, 1996] (tórax, columna lumbar, abdomen y pelvis) añadiendo la columna dorsal. Se procesaron entre 1800 y 23000 exámenes por tipo de examen, con una muestra global de 204660 pacientes adultos examinados en las 3 salas referidas.

Con relación al análisis estadístico, dado que las distribuciones de dosis a pacientes están sesgadas, especialmente en radiología digital, en la parte de las dosis más altas (dado que esas dosis no empeoran la calidad de la imagen), se usó el test no paramétrico de Kruskal-Wallis. Posteriormente, se usó el test de Mann-Whitney para identificar diferencias significativas (1-6) en los valores de dosis anuales, comparando pares de medianas de dosis para cada tipo de examen en años consecutivos. En lugar de usar el habitual punto de corte para el valor de P de 0,05 se asumieron diferencias significativas para valores de P menores de 0,025 para tener en cuenta el hecho de que los datos de cada año eran incluidos 2 veces en las comparaciones. El programa usado para los análisis estadísticos fue el SPSS en su versión 12.0. Dada el reducido número de datos disponibles antes de 1999 no se pudo realizar un análisis estadístico similar para este periodo.

Dado que se usaron grandes muestras (entre 1800 y 23000 exámenes para cada tipo de exploración, la mediana y los valores de los cuartiles son los mejores descriptores estadísticos. Sin embargo, para poder comparar con otros valores de dosis publicados, se determinaron también las medias y las desviaciones estándar. Los valores de dosis fueron comparados con los usados como referencia por la Comisión Europea (EC) y la Asociación Americana de Físicos en Medicina (AAPM) [EC, 1996; Gray, 2005].

3.1.2.- Comparación de la calidad de imagen proporcionada por diferentes tipos de detectores digitales en radiografía de tórax

El **trabajo II** comparó 4 sistemas digitales dedicados a radiología de tórax:

- Un sistema de CR convencional, con digitalizador AGFA ADC Compact Plus y placas de fósforo fotoestimulable en polvo AGFA MD40 (CR1), con una resolución de escaneado de 10 pixeles/mm, y un tamaño de matriz de 3480 x 4248 (35x43 cm).
- Un sistema de CR con digitalizador AGFA DXS y placas de fosforo fotoestimulable estructurado AGFA CR HD 5.0 (CR2). La tecnología de fósforo estructurado en agujas usa un fósforo en forma de cristales que permite mayor densidad de empaquetado que el fósforo en polvo, reduce la dispersión de la luz e incrementa la nitidez en las imágenes. El digitalizador tiene una tecnología en su cabeza de lectura, del tipo línea a línea, con una resolución de escaneado de 50 μ m (20 pixel/mm).
- La primera unidad de panel plano instalada en el centro, en 2001, que fue un General Electric Revolution XQ/i (DR1) con un panel detector de silicio amorfo con centellador de Ioduro de Cesio, un tamaño de matriz de 1936 x 1786 pixel (20 μ m de tamaño de pixel) en un área activa de detector de 41 x 41 cm.
- La unidad de DR más reciente instalada en el Centro (en el momento de realizar el trabajo II) era un Philips Digital Diagnost (DR2) también con un detector de silicio amorfo con centelleador de Ioduro de Cesio, un tamaño de matriz de 3000*3000 pixel (143 μ m de tamaño de pixel) en un área activa de 43*43 cm.

Para la evaluación de la calidad de la imagen se empleó un maniquí específico de contraste-detalle para radiología digital (Artinis CDRAD tipo 2.0). Para simular la dispersión y atenuación en condiciones clínicas se usó un maniquí de polimetil metacrilato (PMMA) de 20 cm de espesor. Se obtuvieron 4 series de imágenes con el misma tensión (125 kVp) a ocho niveles de exposición (0,6, 1, 2, 4, 8,16 32 y 64 mAs) para cubrir un rango suficiente, con valores muy superiores y muy inferiores a los ajustes habituales del control automático de exposición para exploraciones de tórax.

Para evitar la dependencia del observador en la evaluación y calificación de la calidad de imagen, se utilizó un programa de evaluación de la calidad de la imagen diseñado específicamente para el maniquí empleado (Artinis CDRAD Analyser version 1.1) para determinar el umbral de contraste de los 15 orificios circulares con diámetros entre 0,3 y 8,0 mm que componen el maniquí. Para cuantificar la calidad de imagen, se usó el método del inverso de la figura de mérito de la calidad de imagen (IQFi) (2-7):

$$IQFi = 100 / \sum C_i \times D_{i,th}$$

donde $D_{i,th}$ indica el diámetro umbral en la columna de contraste, i y C_i indican los valores de contraste correctamente identificados.

Para medir el kerma en aire en la superficie del detector y del maniquí, se empleó un dispositivo de control de calidad basado en un detector de estado sólido (Unfors Xi con detector Unfors 8202030-B Xi R/F & MAM). Este monitor proporciona para cada exposición, la dosis, el tiempo de exposición el kVp medido y la capa hemirreductora.

Las exposiciones para los sistemas de CR (CR1 y CR2) fueron realizadas en un equipo de rayos X Philips Optimus 50, que cumplía los requisitos del programa de garantía de calidad del Centro, con una reproducibilidad de la exposición mejor del 2% y una exactitud del kVp mejor del 5%. La capa hemirreductora de este equipo era de 4,9 mm Al a 125 kVp. La distancia entre la superficie del maniquí y el foco era de 154 cm y la distancia del foco al detector de imagen era 176 cm.

Los sistemas de panel plano (DR1 y DR2) tenían su propio generador y tubo de rayos X, y se encontraban bajo el mismo programa de garantía de calidad. Todas las modalidades eran mantenidas por sus respectivos fabricantes y seguían sus propios programas de mantenimiento preventivo. La capa hemirreductora para el sistema DR1 era de 4,7 mm Al a 125 kVp. La distancia del foco a la superficie del maniquí era de 161 cm, y la distancia del foco al

detector de imagen era de 182 cm. La capa hemirreductora para el sistema DR2 era de 6,7 mm a 125 kVp. La distancia del foco a la superficie del maniquí era de 165 cm, y la distancia del foco al detector de imagen era de 186 cm.

Las diferencias en distancia en los 4 sistemas eran debidas a la configuración propia de cada sala para exploraciones de tórax. Todas las imágenes fueron realizadas con rejilla antidifusora y fueron procesadas con los parámetros por defecto configurados en cada sala para exploraciones de tórax.

3.1.3.- Dosis a la entrada del paciente pediátrico a partir del índice de exposición en radiografía computarizada.

El **trabajo III** se realizó con el mismo sistema de CR convencional que el trabajo II, un digitalizador AGFA ADC Compact Plus y placas de fósforo fotoestimulable AGFA MD10. Las imágenes fueron procesadas con la aplicación AGFA MUSICA ("Multi Scale Imaging Contrast Amplification"). Adicionalmente se utilizó una aplicación específica para monitorizar el nivel de exposición (AGFA Dose Monitoring Software), calculado como la mediana de los valores logarítmicos del contenido de cada pixel en el lóbulo principal del histograma de la imagen (**Figura 1 del Trabajo III**). Este valor es denominado nivel de exposición o Log M [Agfa, 2000]:

$$\text{Log M} = 2 * \text{Log}(\text{SAL}) - 3.9477$$

donde SAL es el nivel medio de señal, proporcional a los valores del contenido de cada pixel. Debido a la definición logarítmica del nivel de exposición, un incremento de 0,3 significa duplicar la dosis en la placa de fósforo fotoestimulable. En nuestro Centro se utiliza una aplicación de desarrollo local para el control de calidad denominado QCONLINE [Vano, 2005; Vano, 2007] que extrae y transfiere los datos relevantes de la cabecera DICOM de las imágenes enviadas al PACS, a una base de datos. De esta base de datos se han seleccionado y analizado los datos de los equipos de rayos X utilizados para exploraciones pediátricas.

Se han obtenido curvas experimentales relacionando el kerma en aire a la entrada del paciente, con el nivel de exposición, para diferentes valores de kV y espesores de PMMA para simular los tamaños de paciente típicos (con y sin "bucky").

Uno de los problemas en la estimación del kerma en aire a la entrada del paciente en pediatría es la estimación del espesor equivalente de PMMA, que depende no solamente de la edad del niño, sino también de sus características individuales. Otro aspecto importante a ser tenido en cuenta es la heterogeneidad en los tejidos del área examinada en el paciente. Se adoptó un valor de 1,5 [Rassow, 2000] para corregir estas inhomogeneidades solamente en las exploraciones de tórax posteroanterior (PA). No se aplicaron factores de corrección para los resultados obtenidos en el resto de proyecciones (pelvis o abdomen). Solo se evaluaron resultados de dosis de las proyecciones PA o anteroposterior (AP), no evaluando las proyecciones laterales.

Para la estimación del espesor medio del paciente en los grupos de edad seleccionados (<1, 1-5, 6-10 y 11-15 años) para tórax, pelvis y abdomen AP/PA, se usó la metodología del informe NRPB-R318 [NRPB, 2000], no siendo posible usar valores individuales de la relación peso/talla al no disponer de estos datos en los sistemas de información del Centro. El número total de pacientes por edad y tipo de procedimiento analizados se muestran en la **Figura 2 del Trabajo III.**

En cuanto a las medidas, se emplearon 2 equipos de rayos X para obtener el juego de curvas relacionando el kerma en aire a la entrada del paciente y el nivel de exposición: un General Electric MPG 50 y un Philips Optimus 50. Se utilizaron 55 kV (simulando exposiciones entre 0 y 1 año), 70 kV (1-5 años) y 80 kV (>5 años). Las capas hemirreductoras a 80 kV fueron de 3,7 mm Al y 4 mm Al respectivamente para ambos equipos. Para 55 kV fueron de 2,1 mm Al y 2,2 mm Al respectivamente, y 2,8 mm Al para 70 kV en ambos equipos. La geometría de irradiación para obtener las curvas experimentales, simula las condiciones clínicas habituales (180 cm de distancia foco-chasis para "bucky"

mural y 100 cm para exposiciones en mesa). La medida del kerma en aire a la entrada del paciente fue realizada con un dosímetro Radcal 2025 con cámara de ionización plana debidamente calibrada, colocada sobre las láminas de PMMA. Aunque todos los equipos de rayos X disponían de control automático de exposición (excepto los equipos móviles para la unidad de cuidados intensivos) la mayoría de las exposiciones pediátricas de este estudio fueron realizadas con técnica manual. En la **Figura 3 del Trabajo III** se muestra la correlación entre el ESAK y el EL. Las curvas experimentales fueron ajustadas a una función exponencial con coeficientes de correlación próximos a la unidad:

$$\text{ESAK} = A \cdot (\text{edad}) \cdot \exp(B(\text{edad}) \cdot \text{EL})$$

Por tanto, con las suposiciones hechas, es fácil obtener los valores de ESAK si la edad del paciente y el tipo de examen (tórax, pelvis o abdomen) son extraídos de las cabeceras DICOM.

3.1.4.- Análisis de tasa de rechazo de imágenes en radiografía digital usando la información contenida en las cabeceras DICOM.

Para poder realizar un análisis automático de tasas de rechazo en sistemas digitales, el primer requisito es disponer en el PACS de todas las imágenes realizadas y no solamente de las aceptadas. Aunque la mayoría de los sistemas de radiología digital permiten aceptar selectivamente las imágenes generadas y borrar las rechazadas, se solicitó a la Comisión de Garantía de Calidad del HCSC que todas las imágenes producidas (independientemente de si se consideraban diagnósticas o no) fueran enviadas automáticamente al PACS y en paralelo al sistema QCONLINE antes descrito [Vano, 2005] lo cual fue aceptado por la citada Comisión.

En el **trabajo IV**, una vez extraída la información contenida en las cabeceras DICOM de las imágenes e incorporada a una base de datos a través del sistema QCONLINE, el criterio inicial que se utilizó para identificar imágenes potencialmente repetidas, fue que dos o más imágenes tuviesen el mismo número identificador de paciente, la misma modalidad, descripción, proyección

y fecha (**Tabla 1 del Trabajo IV**). Este criterio fue aplicado sobre 3742 imágenes de CR de abdomen y 8236 de tórax archivados en el PACS en 3 meses. Una muestra de esta selección de imágenes potencialmente repetidas fue evaluada por 4 radiólogos independientes para valorar la adecuación del criterio de selección. Después de este análisis se consideró necesario aplicar 4 criterios adicionales de selección (**Tabla 1 del Trabajo IV**), que se aplicaron a las 1893 imágenes de abdomen y 4369 de tórax archivadas en el PACS durante un mes adicional, por 4 radiólogos nuevamente, asignando una causa posible de repetición a cada una para validar el modelo.

3.1.5.- Control de calidad y dosimetría a pacientes en radiología digital. Sistemas en tiempo real: nuevas funcionalidades y transportabilidad.

El sistema QCONLINE anteriormente mencionado fue desarrollado en Microsoft Visual Basic 6,0 con un base de datos bajo Microsoft SQL Server 2005 [Vano, 2005]. Las nuevas funcionalidades incorporadas en el **trabajo V**, permiten el uso de niveles de alarma para valores medios (derivados de un grupo de procedimientos, típicamente los últimos 30) o para pacientes individuales. Cada parámetro auditado en cada imagen entrante puede ser filtrado por modalidad, nombre de estación (equipo de rayos X o digitalizador de CR), descripción del estudio y proyección, con los comparadores mayor que, menor que o igual que o distinto a.

Estas condiciones de alarma individuales pueden sugerir la investigación de las causas de dosis altas o indicar la conveniencia de la inclusión de pacientes sometidos a procedimientos intervencionistas en el protocolo de seguimiento por posibles daños en la piel. Los parámetros técnicos (kV, mAs, tamaño de campo, etc.) y detalles de la práctica operativa (fuerza de compresión en mamografía, elección adecuada del sensor del control automático de exposición en tórax, etc.) son auditados utilizando los datos disponibles en las cabeceras DICOM. Para CR, se auditan el nivel de exposición y los parámetros de post procesado. Para procedimientos intervencionistas, se consideran el número de imágenes por serie, el número total de series y el número total de imágenes por procedimiento para la generación de alarmas. Cuando algunos

equipos de rayos X incluyen en las cabeceras DICOM el producto kerma área y el kerma en aire acumulado en el punto de referencia de entrada al paciente (antes llamado punto de referencia intervencionista), estos valores pueden ser usados para generar alarmas.

El sistema QCONLINE ha sido preparado para ser distribuido a algunos servicios de Radiodiagnóstico de la Comunidad de Madrid interesados en participar en su ensayo y poder posteriormente extenderse a otros centros de España o de Europa.

Con similar metodología se ha preparado un servidor de MPPS SCP para recibir información sobre los parámetros de adquisición, dosis a pacientes y otros datos relacionados con el estudio completo, una vez que éste ha sido finalizado en la modalidad.

3.2.- Procedimientos guiados por fluoroscopia.

3.2.1.- Valores de dosis en piel y producto dosis por área en procedimientos de cardiología intervencionista.

El **trabajo VI** fue realizado en 3 centros diferentes monitorizando procedimientos de COR y ACTP, con 3 equipos diferentes de cardiólogos, sobre una muestra no seleccionada de pacientes de los que se recogieron los datos más relevantes, estando todos los equipos dotados de intensificador de imagen. Uno de los centros era el HCSC con 2 laboratorios dedicados procedimientos de CI: el primero con un Philips Integris HM3000 configurado específicamente para CI, incorporando un sistema de alta filtración ("SpectraBeam") identificado como HC-I y el segundo con un Philips Optimus M-200, identificado como HC-O. Los otros dos centros, identificados como RI y RJB, estaban ambos equipados con sistemas General Electric ADVANTX configurados para estudios cardiológicos y vasculares. Solamente el sistema HC-I estaba equipado con cámara de transmisión para la medida del producto dosis por área. La constancia del rendimiento de los equipos de rayos X era

medida periódicamente como parte del programa de garantía de calidad, con resultados satisfactorios.

Se realizó dosimetría con películas lentas utilizando el modelo Kodak X-Omat V, comúnmente disponibles en hospitales con equipos de radioterapia. Previamente se efectuaron pruebas de sensitometría y calibración para medidas de dosis en calidades de haz típicas de procedimientos de cardiología (6-23). Las películas fueron procesadas en una reveladora Kodak X-Omat-M6B (con productos químicos Kodak). La densidad óptica fue medida con un densitómetro Nuclear Associates Victoreen 07-424. La dosis más alta legible en la parte lineal de la curva sensitométrica era alrededor de 700 mGy, un valor superior a las dosis habitualmente medidas en la mayoría de los procedimientos. Sin embargo, debe hacerse notar que la precisión de los valores en el hombro de la curva sensitométrica fue bastante pobre.

Para las medidas de dosis a la entrada de los pacientes, también se emplearon entre cuatro y ocho dosímetros de termoluminiscencia de fluoruro de litio (Harshaw TLD-100), calibrados individualmente en las energías de los rayos-X diagnósticos, colocándolos en contacto con las películas lentas en las posiciones donde eran esperables las máximas exposiciones. Los datos de ambos sistemas, películas y dosímetros, fueron usados conjuntamente, empleando los últimos, para reducir la incertidumbre en las zonas más irradiadas para la estimación de la dosis máxima en piel.

El sistema de lectura de los dosímetros de termoluminiscencia era un Harshaw 4400. Las medidas de producto dosis por área fueron realizadas con una cámara de transmisión PTW-Freiburg Diamentor. La exactitud de la cámara de transmisión y el sistema de dosimetría por termoluminiscencia fue comprobada por comparación con las lecturas realizadas con una cámara de ionización calibrada Victoreen Rad-Check, de donde se obtenían los factores de corrección apropiados. La exactitud de las medidas estuvo dentro de un 12% para la cámara de transmisión, con una incertidumbre (en la medida de la precisión) no mayor de un 15%. La incertidumbre de las lecturas de los dosímetros de termoluminiscencia estuvo por debajo de 7% para el rango de

dosis en que se desarrolló el trabajo. Los errores en la estimación de dosis debidos a cambios en la velocidad de las películas y su contraste en el rango de energías usadas fueron inferiores al 10%. Las dosis determinadas con películas y dosímetros de termoluminiscencia resultaron compatibles, con discrepancias por debajo del 15%. Las incertidumbres señaladas incluyen los cambios en la respuesta del detector con las diferentes calidades del haz utilizadas.

Para estimar la concentración (solapamiento) de los campos de radiación durante un procedimiento, se estimó un factor de concentración, calculando la relación entre la máxima dosis en piel y la dosis media obtenida como el cociente del producto dosis por área y el área total irradiada. Si un procedimiento se realiza con campos de radiación a menudo localizados en las mismas zonas de la piel, el factor de concentración tendrá un valor más alto que en otro procedimiento donde los campos estén más distribuidos.

Se realizó una estimación del tiempo típico y el número de imágenes en proyecciones laterales (no reflejadas en la película colocada bajo el paciente), basada en controles previos y en la opinión del facultativo que realiza el procedimiento, así como el área total irradiada. El tamaño medio de los campos fue calculado a partir de las áreas ennegrecidas en la película lenta, y el cociente entre el producto dosis por área y el tamaño medio del campo de radiación, permitía obtener el valor del kerma en aire incidente a la entrada del paciente.

3.2.2.- Es necesario evitar el incremento en las dosis a los pacientes cuando se actualizan los sistemas de cardiología intervencionista con detectores de panel plano.

En el **trabajo VII** se registraron las medidas de dosis a pacientes en 1040 COR y 1085 ACTP, realizadas entre marzo de 2009 y marzo de 2010. Los procedimientos fueron realizados en dos salas dedicadas a CI por especialistas entrenados o por becarios supervisados por estos especialistas y los

procedimientos realizados se pueden considerar de similar nivel de complejidad.

Los equipos de rayos X estaban sometidos al programa de garantía de calidad del HCSC, incluyendo pruebas de constancia periódicas para evaluar la tasa de dosis a la entrada del receptor de imagen y a la entrada de diferentes espesores de PMMA y cobre, siguiendo el protocolo propuesto por el consorcio Europeo DIMOND [Faulkner, 2001]. A los dos sistemas de rayos X se les realizaron medidas periódicas de la calidad de la imagen y controles de calidad para verificar que se mantenían de acuerdo a las especificaciones del fabricante, así como a los niveles de referencia establecidos en las pruebas de aceptación.

Se registraron los valores del producto dosis por área, junto con el tiempo de escopia y el número total de imágenes adquiridas. Se registraron valores de 698 COR y 376 ACTP realizadas durante los 6 meses antes de la actualización de ambos sistemas Philips Integris H5000 con intensificador de imagen a Philips Allura XPER FD10 con panel plano (que se realizó en septiembre de 2009). Los mismos datos fueron recogidos para 342 procedimientos de COR y 709 de ACTP, durante los primeros 6 meses de funcionamiento de los sistemas una vez instalados los paneles planos. Dado que el personal de operación, la complejidad y la forma de realizar los procedimientos permanecieron básicamente sin alteraciones, cualquier cambio en las dosis a los pacientes podía suponerse atribuido básicamente, al cambio en los ajustes y protocolos de usuario para la fluoroscopia y los modos de adquisición en cine entre los equipos antes y después de la instalación de los detectores de imagen de panel plano. En ambos casos el producto dosis por área fue medido con las cámaras de transmisión calibradas incorporadas a los equipos.

3.2.3.- Sistemas de manejo automático de parámetros dosimétricos en radiología y cardiología intervencionistas.

El **trabajo VIII** presenta el sistema automático denominado “Dose on Line for Interventional Radiology” (DOLIR) que es la continuación de trabajos previos

realizados durante las Acciones de Investigación Europeas DIMOND y SENTINEL [Faulkner, 2005; Faulkner, 2008]. El sistema puede ser considerado como una solución temporal hasta que los informes de dosis estructurados DICOM (DICOM DOSE SR) estén disponibles. A partir de la experiencia previa con estándares similares, se estima que serán necesarios entre 3 y 5 años para que la industria los implemente en la mayoría de los centros sanitarios. Adicionalmente, DOLIR incluye algunas funcionalidades que pueden ser usadas con los futuros DICOM DOSE SR.

DOLIR ha sido implementado con los sistemas de cardiología y radiología intervencionista de marca Philips existentes en el HCSC: un Allura FD-20 (dedicado a RI general periférica), un biplano Allura FD-20/FD-10 (dedicado a neurorradiología intervencionista) y cinco Allura FD-10 dedicados a CI y uno a electrofisiología cardíaca.

Todos estos sistemas tienen la capacidad de exportar al final del estudio, mediante un mensaje de correo electrónico, un informe de dosis al paciente que incluye información del paciente, del estudio y de cada una de las series de imágenes adquiridas (incluso las series de fluoroscopia si el operador decide grabar las imágenes). Se instaló un servidor de correo electrónico comercial en la intranet del centro (Ability Mail Server) para poder recibir estos mensajes de todos los sistemas. Se realizó una aplicación con conectividad de cliente POP3 para solicitar y recuperar todos los informes y almacenar su contenido en una base de datos sobre Microsoft SQL Server.

Una funcionalidad destacable del sistema es la definición de una serie de niveles de alarma para alertar al Servicio de Física Médica en caso de cualquier evento relevante relacionado con las dosis a los pacientes o los protocolos de operación. Por un lado, alarmas individuales de dosis a paciente que permitan iniciar un seguimiento sobre posibles efectos deterministas en piel, y por otro lado, alarmas sobre las medianas de los últimos 30 procedimientos en caso de que pudiesen ser superiores a los niveles de referencia de los correspondientes procedimientos. Otras posibles alarmas valoradas han sido las distancias del foco al detector de imagen (distancias

grandes indican falta de optimización) o uso reiterado de tasas altas de adquisición de imágenes de cine (p.e. 30 im/s en vez del estándar a 15 im/s).

4.- Discusión Integradora

La transición de sistemas de imagen radiológicos convencionales a digitales ha sido muy distinta en radiología de proyecciones de la de los procedimientos guiados por fluoroscopia, especialmente la radiología y cardiología intervencionistas. En radiología de proyecciones la transición ha sido más brusca y ha estado ligada al cambio en el detector de imagen, ya sea por la incorporación de sistemas de CR, aprovechando los equipos de rayos X existentes, como mediante la incorporación de nuevos equipos de rayos X con detectores de DR. En procedimientos guiados por fluoroscopia el cambio a técnicas digitales ha sido mucho más gradual, ya que se comenzó con una digitalización de las imágenes adquiridas con intensificador de imagen, en alguno de los puntos de la cadena de televisión, y se está completando con la sustitución del intensificador de imagen por detector de panel plano en equipos dedicados a intervencionismo. Mientras tanto, en la mayor parte de equipos con fluoroscopia dedicados a procedimientos considerados como no intervencionistas (para exploraciones de digestivo, urología y equipos radioquirúrgicos) esta transición no se ha completado, siendo todavía una transición parcial o con utilización de equipos todavía totalmente analógicos. Esto, junto con las diferencias específicas en los procedimientos para la dosimetría a pacientes, ha motivado que en los apartados anteriores se hayan mantenido por separado los trabajos relativos a estas dos áreas.

En radiología de proyecciones, a la hora de evaluar el impacto que ha supuesto la radiología digital sobre las dosis de radiación a los pacientes y a la calidad de las imágenes obtenidas, se han valorado diferentes aspectos, como son las variaciones en las dosis a los pacientes al poner en marcha sistemas digitales, la calidad de imagen obtenida con los diferentes sistemas de imagen digital, la forma de evaluar dosis a pacientes a partir de los nuevos índices que aportan algunos sistemas digitales, la dificultad en la evaluación de tasas de rechazo con sistemas digitales y el aprovechamiento de las ventajas que aportan los

sistemas digitales para auditar las dosis a los pacientes y controlar la calidad de los procedimientos en tiempo real.

En cuanto al impacto en las dosis, los resultados del **trabajo I** muestran que los valores de las medianas de las dosis a la entrada de los pacientes aumentaron entre un 40% y un 103% tras la puesta en marcha de sistemas digitales de tipo CR (Tabla 1 del trabajo I). Estos incrementos detectados en el primer trimestre de funcionamiento fueron corregidos durante el primer año, y se alcanzaron reducciones de dosis superiores una vez que se aplicaron medidas correctoras y se implementaron acciones de optimización (**Figura 1 del Trabajo I**). Se alcanzaron unos niveles de dosis en el rango de un 15%-38% de los niveles de referencia Europeos para radiografía con cartulina-película [EC, 1996], y entre un 28%-41% de los valores recomendados por la APPM [Gray, 2005]. Esto representó una reducción de entre un 20% y un 50% de los valores iniciales de dosis a los pacientes para CR.

La calidad de imagen que se puede obtener con diferentes sistemas digitales en relación a las dosis necesarias, fue evaluada en el **trabajo II** donde se presentan los valores de calidad de imagen (como IQFi) frente al kerma en aire incidente con rejilla para 4 sistemas de imagen diferentes (**Figura 1 del Trabajo II**). Los resultados obtenidos muestran que los sistemas más modernos (tanto de CR como de DR) proporcionan mejor calidad de imagen, con una tendencia a mejores resultados en sistemas de DR con dosis más bajas. Como también manifiestan otros autores [Bush, 2003; Fishbach, 2002; Geijer, 2001; Peer, 2001] los sistemas de DR tienen mayor potencial para proporcionar una elevada calidad de imagen cuando se reduce la dosis, si bien algunos sistemas de CR como el CR2 con fósforos estructurados también pueden proporcionar una elevada calidad de imagen, comparable o superior a algunos sistemas DR.

Las imágenes de DR incluyen en sus cabeceras DICOM información técnica suficiente para la estimación de las dosis a los pacientes de manera automática con las correcciones oportunas (y la necesaria calibración periódica). Sin embargo en los sistemas de CR, al ser la parte de imagen independiente de la

generación de rayos X, no existe en la mayoría de los casos, información técnica que permita la evaluación directa de las dosis a los pacientes. El único indicador presente es un índice de dosis relativo a la luz emitida por el fósforo fotoestimulable. En el **trabajo III** se utilizó este nivel de exposición (**Figura 1 del Trabajo III**) para calcular las dosis a los pacientes (**Tabla 1 del Trabajo III**) en una muestra considerable de exploraciones pediátricas (**Figura 2 del Trabajo III**), siendo la principal fuente de incertidumbre, el desconocimiento del peso y talla de los pacientes, aunque de acuerdo a los resultados obtenidos, el disponer de muestras lo suficientemente grandes compensa estas incertidumbres y las medianas obtenidas son representativas de las dosis a los pacientes para cada rango de edad y tipo de estudio. La incorporación automática de algunos de estos datos de los pacientes (peso y talla, entre otros) es un reto que la industria radiológica está considerando en las nuevas generaciones de equipos de radiodiagnóstico.

Los tres pilares clásicos de un programa de garantía de calidad en radiodiagnóstico son la evaluación de dosis a los pacientes, la evaluación de la calidad de imagen y el análisis de tasas de rechazo o repetición. Este último parámetro se ve dramáticamente alterado con la introducción de sistemas digitales. Del simple recuento de placas rechazadas en un cajón con sistemas de película radiográfica, pasamos a tener múltiples dificultades en la evaluación de las imágenes repetidas. Su evaluación se complica por la facilidad con la que los sistemas digitales permiten la repetición de una imagen y el borrado de la anterior, la dificultad de identificar la sala en la que se realizó una imagen cuando un sistema de CR atiende a varias salas y la identificación de las imágenes repetidas por no disponer de toda la información diagnóstica necesaria.

En el **trabajo IV** se aplicó una metodología de identificación de imágenes repetidas basada en la información contenida en las cabeceras DICOM de imágenes de CR que en sus primeros resultados mostró la necesidad de considerar criterios de selección adicionales (por ejemplo la orientación del chasis en CR en vertical u horizontal) permitiendo de manera automática seleccionar imágenes potencialmente repetidas, que tras su evaluación

individualizada por los radiólogos, resultó ser aproximadamente un 50% de las seleccionadas automáticamente como potencialmente repetidas, debido a la incorrecta identificación del paciente, paciente demasiado grande para el tamaño del detector, placa no expuesta o expuesta sin paciente. Las tasas de rechazo finalmente obtenidas, resultaron ser muy bajas (0,9% en exploraciones de tórax y 3,3% en exploraciones de abdomen frente al 10-15% típico de sistemas cartulina -película), si bien no se detectan otras causas de repetición como imágenes tomadas en días distintos pero innecesarias, imágenes repetidas con diferente identificación, o repeticiones debidas a orientación errónea del chasis en su primera exposición. Otros estudios [Honea, 2002; Peer, 1999; Peer, 2001] habían descrito como principal causa de repetición en sistemas de cartulina película los problemas de exposición y procesado, mientras que en sistemas digitales la principal causa es un incorrecto posicionamiento del paciente, como también se muestra en este trabajo.

La dosimetría a pacientes en procedimientos intervencionistas resulta más compleja que en radiología de proyecciones. En el **trabajo VI** se presentaron los resultados de una evaluación manual sobre 26 COR y 7 ACTP con un análisis completo del producto dosis por área y parámetros técnicos, medidas con dosímetros de termoluminiscencia y colocación de películas lentas bajo el paciente. Por un lado sientan las bases metodológicas de los protocolos de evaluación dosimétrica en procedimientos intervencionistas antes de la implantación completa de sistemas digitales y por otro se destacan las dificultades asociadas a la toma manual de datos y a lo reducido de las muestras analizables, junto a la dificultad de establecer niveles de referencia dada la variabilidad de los procedimientos y sus diferentes grados de complejidad. Se pone de manifiesto la dificultad de establecer correlaciones entre los diferentes parámetros (por ejemplo entre la dosis en piel y producto dosis por área) que en trabajos posteriores se simplificará al disponer de grandes muestras aprovechando las posibilidades de recogida automática de los datos que permiten los sistemas digitales.

En el caso de los procedimientos de cardiología intervencionista el **trabajo VII** pone de manifiesto que la fase definitiva de implantación de tecnologías

digitales, consistente en la sustitución del intensificador de imagen por paneles planos, puede conllevar un incremento significativo en el producto dosis por área sin una variación importante del tiempo de escopia ni del número de imágenes adquiridas (**Tablas 1 y 2 del Trabajo VII**). Dado que tanto los especialistas que realizaban los procedimientos como la complejidad de los mismos permanecieron sin variaciones, la principal causa de este incremento de las dosis fue el ajuste de los parámetros del equipo de rayos X para el nuevo sistema de imagen (además de los campos de radiación algo mayores y la falta de colimación y de utilización, en muchos casos, de los filtros en cuña semitransparentes). Estos resultados son compatibles con los publicados por otros autores [Trianni, 2005] aunque hay otros trabajos en los que no se observó variación [Davies, 2007].

La implantación de sistemas digitales ha supuesto nuevas fuentes de información en lo relativo a la dosimetría a pacientes tanto en radiología de proyecciones como en procedimientos guiados por fluoroscopia, al disponer de parámetros técnicos y dosimétricos junto a las imágenes en sus cabeceras DICOM, o en otros servicios DICOM como el MPPS o el informe estructurado de dosis. En todos los trabajos anteriores se han utilizado diferentes aproximaciones para emplear como herramienta, la explotación de esta información. En el **Trabajo V** se presentan una serie de funcionalidades del sistema QCONLINE que permiten auditar cualquier parámetro incluido en la cabecera DICOM, configurando alarmas para valores medios en un grupo de imágenes o valores específicos en imágenes individuales. En el **trabajo VIII** se presenta otra aproximación basada en el aprovechamiento de los informes de dosis que pueden enviar por correo electrónico algunos equipos para procedimientos intervencionistas (**Tabla 1 del Trabajo VIII**). Hasta que la industria radiológica implante el informe estructurado de dosis DICOM [IEC, 2007], los informes de dosis enviados por correo electrónico y el servicio MPPS son herramientas útiles complementarias para auditar parámetros dosimétricos en procedimientos intervencionistas. La transportabilidad de este tipo de sistemas ha sido evaluada y cabe esperar que más centros incorporarán estos sistemas en el futuro.

5.- Conclusiones

1. Las dosis a los pacientes se pueden incrementar considerablemente en el proceso de transición de radiología convencional con cartulina-película a radiología digital. Esto hace necesario aplicar programas de gestión de las dosis que incorporen entrenamiento específico para los técnicos especialistas en imagen y auditorias frecuentes o permanentes de las dosis a los pacientes, lo que puede permitir mejorar la práctica y mantener o incluso reducir las dosis a los pacientes por debajo de los valores previos a la implantación de los sistemas digitales.

2. La calidad de imagen de los sistemas digitales ha mejorado desde los primeros sistemas CR y DR a los actuales, así como su potencial de reducción de dosis. Los modernos sistemas de CR de fósforos estructurados pueden proporcionar imágenes de igual o mayor calidad que los sistemas DR con dosis de radiación similares. Sin embargo, los sistemas DR presentan el mayor potencial de reducción de dosis manteniendo una adecuada calidad de imagen.

3. Los sistemas de DR incorporan en las cabeceras de sus imágenes DICOM información técnica suficiente para realizar evaluaciones automáticas de dosis a los pacientes. Los sistemas de CR no disponen de tal información, pero a partir del indicador de nivel de exposición que incorporan y con algunas medidas experimentales previas de calibración y ciertas aproximaciones, se pueden calcular niveles de dosis indicativos para diferentes tipos de exploración sobre grandes muestras de pacientes.

4. La evaluación de tasas de rechazo en sistemas digitales precisa la aplicación de nuevas metodologías, en donde es posible aprovechar la información contenida en las cabeceras DICOM para detectar de manera automática imágenes potencialmente repetidas, y aunque es necesaria una revisión manual para depurar las realmente repetidas, permite detectar deficiencias en el funcionamiento de un departamento de radiología digital como identificación

incorrecta del paciente, errores de posicionamiento, técnica radiológica inadecuada, procesamiento incorrecto de la imagen, averías en los equipos, artefactos, etc. Adicionalmente, las imágenes rechazadas seleccionadas automáticamente pueden ser empleadas para la formación continuada del personal.

5. En procedimientos intervencionistas el paso de sistemas con intensificador de imagen a sistemas con paneles planos, puede suponer incrementos significativos en las dosis a los pacientes, atribuibles principalmente a los nuevos ajustes del equipo de rayos X que realiza el fabricante para el panel plano y a ciertos defectos en los procedimientos de operación (como la falta de colimación y utilización de los filtros en cuña). En estas situaciones es necesario aplicar programas de optimización a los protocolos clínicos y a los ajustes del fabricante.

6. El paso a sistemas digitales, tanto en radiología de proyecciones como en procedimientos guiados por fluoroscopia aporta la posibilidad de poner en marcha sistemas automatizados de dosimetría a pacientes y control de parámetros técnicos. Este tipo de sistemas deberán permitir la evaluación de dosis a los pacientes en la mayoría de procedimientos y que el valor de dosis de cada estudio pueda figurar, junto con las imágenes, en la historia del paciente. Otra funcionalidad esencial es la ayuda en la identificación de pacientes sometidos a procedimientos intervencionistas donde se pueda haber alcanzado el umbral de aparición de efectos deterministas en piel y sea aconsejable aplicar un protocolo de seguimiento.

6.- Bibliografía

[Agfa, 2000] Agfa ADC System Manual Image Processing. 2000. Section 10.

[Arvanitis, 1991] Arvanitis TN, Parizel PM, Degryse HR, Schepper AMA. Reject analysis: a pilot programme for image quality management. Eur J Radiol 1991;12(3):171-176.

[Azevedo, 2006] Azevedo ACP, Osibote OA, Boechat MCB. Paediatric x-ray examinations in Rio de Janeiro. Phys Med Biol 2006;51:3723-32.

[Betsou, 1998] Betsou S, Efstathopoulos EF, Katrasis D, Faulkner K, Panayiotakis G. Patient radiation doses during cardiac catheterization procedures. Br J Radiol 1998;71:634-9.

[BIR, 1998] British Institute of Radiology. Quality Assurance in the Diagnostic X-ray Department. British Institute of Radiology 1998.

[Bogaert, 2008] Bogaert E, Bacher K, Lapere R, Thierens H. Does digital flat detector technology tip the scale towards better image quality or reduced patient dose in interventional cardiology? Eur J Radiol 2008;72:348-353.

[Boone, 2002] Boone JM, Cody DD, Fisher JR et al. Quality Control in Diagnostic Radiology. Diagnostic X-ray Imaging Committee Task Group 12, AAPM report no. 74. American Association of Physicist in Medicine. Medical Physics Publishing 2002.

[Busch, 2003] Busch HP, Busch S, Decker C, Schilz C. [Image quality and exposure dose in digital projection radiography] Rofo 2003;175(1):32-37. In German.

[Cascade, 1987] Cascade PN, Peterson LE, Wajszczuk WJ, Mantel J. Radiation exposure to patients undergoing percutaneous transluminal coronary angioplasty. *Am J Cardiol* 1987;59:996-7.

[Compagnone, 2005] Compagnone G, Pagan L, Bergamini C. Local diagnostic reference levels in standard x-rays examinations. *Radiat Prot Dosim* 2005;113:54-63.

[Davies, 2007] Davies A, Cowen A, Kengyelics S, Moore J, Sivananthan M. Do flat detector cardiac X-ray systems convey advantages over image-intensifier based systems? Study comparing X-ray dose and image quality. *Eur Radiol* 2007;17:1787-1794.

[Dunn, 1998] Dunn MA, Roger AT. X-ray film reject analysis as a quality indicator. *Radiography* 1998;4:29-31.

[EC, 1996] European Commission. European Guidelines on quality criteria for diagnostic radiographic images. Report EUR 16260. Office for the Official Publications of the European Communities. 1996.

[EC, 1997] European Commission. Council Directive on Health Protection of Individuals Against Dangers of Ionising Radiation in Relation to Medical Exposures, and replacing Directive 84/466/EURATOM. 97/43/EURATOM. Office for the Official Publications of the European Communities. 1997.

[Fajardo, 1995] Fajardo LC, Geise RA, Ritenoure RA. A survey of film for use as a dosimeter in interventional radiology. *Health Phys* 1995;68:595-9.

[Faulkner, 2001] Faulkner K. Introduction to constancy check protocols in fluoroscopic systems. *Radiat Prot Dosim* 2001;94(1-2):65-68.

[Faulkner, 2005] Faulkner K. The DIMOND project and its impact on radiation protection. *Radiat Prot Dosim* 2005;117(1-3):3-6.

[Faulkner, 2008] Faulkner K, Malone J, Vano E, padovani R, Busch HP, Zoetelief JH, Bosmans H. The SENTINEL project. Radiat Prot Dosim 2008;129(1-3):3-5.

[Federman, 1994] Federman J, Bell MR, Wondrow MA, Grill DE, Holmes DR. Does the use of new intracoronary interventional devices prolong radiation exposure in the cardiac catheterization laboratory? J Am Coll Cardiol 1994;23:347-51.

[Fischbach, 2002] Fischbach F, Ricke J, Freund T, Werk M, Spors B, Baumann C, Pech MJ, Felix R. Flat panel digital radiography compared with storage phosphor computer radiography: assessment of dose versus image quality in phantom studies. Invest Radiol 2002;37(11):609-614.

[Freedman, 1995] FreedmanM, Steller D, Jafroudi H, Mun SK. Quality control of storage phosphor digital radiography systems. J Digit Imaging 1995;8(2):67-74.

[Gadeholt, 1989] Gadeholt G, Geitung JT, Göthlin JH, Asp T. Continuing reject-repeat film analysis program. Eur J Radiol 1989;9(3):137-141.

[Geijer, 2001] Geijer H, Beckman KW, Anderson T, Persliden J. Image quality vs. radiation dose for a flat-panel amorphous silicon detector: a phantom study. Eur Radiol 2001;11(9):1704-1709.

[Geise, 1990] Geise RA, Ansel HJ. Radiotherapy verification film for estimating cumulative entrance skin exposure for fluoroscopic examinations. Health Phys 1990;59:295-8.

[Gray, 2005] Gray JE, Archer BR, Butler PF, et al. Reference values for diagnostic radiology: application and impact. Radiology 2005;235:354-358.

[Hardy, 2001] Hardy M, Persaud A. The challenge of governance: achieving quality in diagnostic imaging. Radiography 2001;7:159-163.

[Honea, 2002] Honea R, Blado ME, Ma Y. Is reject analysis necessary after converting to computed radiography? J Digit Imaging 2002;15(suppl 1):41-52.

[ICRP, 1991] International Commission on Radiological Protection. 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Ann. ICRP 21. 1991.

[ICRP, 1996] International Commission on Radiological Protection. Radiological protection and safety in medicine. ICRP Publication 73. Ann. ICRP 26(2). 1996.

[ICRP, 2000] International Commission on Radiological Protection. Avoidance of radiation injuries from medical interventional procedures. ICRP Publication 85. Ann. ICRP 30(7). 2000.

[ICRP, 2004] International Commission on Radiological Protection. Managing Patient Dose in Digital Radiology. ICRP Publication 93. Ann. ICRP 34(1). 2004.

[ICRP, 2007] International Commission on Radiological Protection. The 2007 recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37(2-4). 2007.

[ICRP, 2008] International Commission on Radiological Protection. Radiological protection in medicine. ICRP Publication 105. Ann. ICRP 37(6). 2008.

[IEC, 2007] IEC. New work item proposal. Medical electrical equipment. Radiation dose documentation. Part 1: Equipment for radiography and radioscopy. 62B/645/NP. Date of circulation 2007-01-19.

[Karppinen, 1995] Karppinen J, Parviainen T, Servomaa A, Komppa T. Radiation risk and exposure of radiologists and patients during coronary angiography and percutaneous transluminal coronary angioplasty (PTCA). Radiat Prot Dosim 1995;57:481-5.

[Khoury, 2003] Khoury HJ, Oliveira M. Influencia do procedimento radiografico na dose de entrada na pele de pacientes em radiologia pediatrica. Radiol Brasileira 2003;36:105-9.

[Kiljunen, 2007] Kiljunen T, Jarvinen H, Savolainen S. Diagnostic reference levels for thorax x-ray examinations of paediatric patients. Br J Radiol 2007;80:452-9.

[Koenig, 2001] Koenig TR, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: Part 1, Characteristics of radiation injury. Am J Roentgenol 2001;177(1):3-11.

[Koenig, 2001b] Koenig TR, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: Part 2, Review of 73 cases and recommendations for minimizing dose delivered to patient. Am J Roentgenol 2001;177(1):13-20.

[LeHeron, 1992] LeHeron JC. Estimation of effective dose to the patient during medical x-ray examinations from measurements of dose-area product. Phys Med Biol 1992;37:2117-26.

[Martin, 1995] Martin CJ. Measurement of patient entrance surface dose rates for fluoroscopic x-ray units. Phys Med Biol 1995;40:823-4.

[McParland, 1998] McParland BJ. Entrance skin dose estimates derived from dose-area product measurements in interventional radiological procedures. Br J Radiol 1998;71:1288-95.

[Meier, 1997] Meier B. Radiation exposure in the cardiac catheterization laboratory: an issue or a non-issue. Cathet Cardiovasc Diagn 1997;40:352.

[Mohamadain, 2004] Mohamadain KEM, da Rosa LAR, Azevedo ACP, Guebel MRN, Boechat MCB, Habani F. Dose evaluation for paediatric chest x-ray

examinations in Brazil and Sudan: low doses and reliable examinations can be achieved in developing countries. *Phys Med Biol* 2004;49:1017-31.

[Montgomery, 2000] Montgomery A, Martin CJ. A study of the application of paediatric reference levels. *Br J Radiol* 2000;73:1083-90.

[Nol, 2006] Nol J, Isouard G, Mirecki J. Digital repeat analysis; setup and operation. *J Digit Imaging* 2006;19(2):159-166.

[NRPB, 2000] National Radiological Protection Board. Reference doses and patient size in paediatric radiology. NRPB-R318 2000.

[NRPB, 2002] National Radiological Protection Board. Doses to Patients from Medical X-Ray Examinations in the UK – 2000 Review. NRPB-w14 2002.

[Patee, 1993] Patee PL, Johns PC, Chambers RJ. Radiation risk to patients from percutaneous transluminal coronary angioplasty. *J Am Coll Cardiol* 1993;22:1044-51.

[Peer, 1999] Peer S, Peer R, et al. Comparative reject analysis in conventional film-screen and digital storage phosphor radiography. *Eur Radiol* 1999;9(8):1693-1696.

[Peer, 2001] Peer S, Neitzel U, Giacomuzzi SM, Peer R, Gassner E, Steingruber I, Jaschke W. Comparison of low-contrast detail perception on storage phosphor radiographs and digital flat panel detector images. *IEEE Trans Med Imaging* 2001;20(3):239-242.

[Peer, 2001b] Peer S, Peer R, et al. Comparative reject analysis in conventional film-screen and digital storage phosphor radiography. *Radiat Prot Dosim* 2001;94(1-2):69-71.

[Peters, 2002] Peters SE, Brennan PC. Digital radiography: are the manufacturers' settings too high? – optimization of the Kodak digital

radiography system with aid of the computed radiography dose index. Eur Radiol 2002;12:2381-2387.

[Pitcher, 1992] Pitcher EM, Wells PN. Quality assurance and radiologic audit. Curr Opin Radiol 1992;4(3):9-14.

[Pratt, 1993] Pratt TA, Shaw AJ. Factors affecting the radiation dose to the lens of the eye during cardiac catheterization procedures. Br J Radiol 1993;66:346-50.

[Rassow, 2000] Rassow J, Schmaltz AA, Hentrich F, Streffer C. Effective doses to patients from paediatric cardiac catheterization. Br J Radiol 2000;73:172-83.

[Spahn, 2005] Spahn M. Flat detectors and their clinical applications. Eur Radiol 2005;15(9):1934-1947.

[Stern, 1995] Stern SH, Rosenstein M, Renaud L, Zankl M. Handbook of selected tissue doses for fluoroscopic and cineangiographic examination of coronary arteries. HHS Publication FDA 95-8289. US Department of Health and Human Services, 1995.

[Ten, 1998] Ten JI, Vano E, Fernandez JM, Guibelalde E. CARDIODOSE ver 1.0 software for estimating effective and organ dose in interventional cardiology. Madrid: medical Physics Group, radiology Department, Complutense University, 1998.

[Trianni, 2005] Trianni G, Padovani R. Are new technologies always reducing patient doses in cardiac procedures? Radiat Prot Dosim 2005;117:97-101.

[Tsapaki, 2004] Tsapaki V, Kottou S, Kollaros N, Dafnomilli P, Koutelou M, Vano E, Neofotistou V. Comparison of a conventional and a flat-panel digital system in interventional cardiology procedures. Br J Radiol 2004;77(919):562-567.

[Vano, 1995] Vano E, Gonzalez L, Fernandez JM, Guibelalde E. Patient dose values in interventional radiology. Br J Radiol 1995;68:1215-20.

[Vano, 1997] Vano E, Guibelalde E, Fernandez JM, Gonzalez L, Ten JI. Patient dosimetry in interventional radiology using slow film systems. Br J Radiol 1997;70:195-200

[Vano, 1998] Vano E, Arranz L, Sastre JM, Moro C, Ledo A, Garate MT, Minguez I. Dosimetric and radiation protection considerations based on some cases of patient skin injuries in interventional cardiology. Br J Radiol 1998;71:510-516.

[Vano, 2001] Vano E, Goicolea J, Galvan C, Gonzalez L, Meiggs L, Ten JI, Macaya C. Skin radiation injuries in patients following repeated coronary angioplasty procedures. Br J Radiol 2001;74(887):1023-1031.

[Vano, 2002] Vano E, Fernandez JM, Ten JI, Guibelalde E, Gonzalez L, Pedrosa CS. Real-time measurement and audit of radiation dose to patients undergoing computed radiography. Radiology 2002;225:283-288.

[Vano, 2005] Vano E, Fernandez JM, Ten JI, Gonzalez L, Guibelalde E, Prieto C. Patient dosimetry and image quality in digital radiology from online audit of the x-ray system. Radiat Prot Dosim 2005;117:199-203.

[Vano, 2007] Vano E, Fernandez JM, Ten JI, Prieto C, Gonzalez L, de las Heras H. Transition from screen-film to digital radiography: evolution of patient radiation doses at projection radiography. Radiology 2007;243:461-6.

[Wagner, 1994] Wagner LK, Eifel PJ, Geise RA. Potential biological effects following high x-ray dose interventional procedures. J Vasc Interv radiol 1994;5:71-84.

[Wagner, 1998] Wagner LK. Typical doses and biological implications. RSNA categorical course in diagnostic radiology physics: cardiac catheterization imaging. RSNA 1998:249-54.

[Wagner, 1999] Wagner LK, MacNeese MD, Marx MV, Siegel EL. Severe skin reactions from interventional fluoroscopy: case report and review of literature. Radiology 1999;213:773-6.

[Weatherburn, 2000] Weatherburn GC, Bryan S, Davies JG. Comparison of doses for bedside examinations of the chest with conventional screen-film and computed radiography: results of a randomized controlled trial. Radiology 2000;217:707-712.

[Zorzetto, 1997] Zorzetto M, Bernardi G, Morocutti G, Fontanelli A. Radiation exposure to patients and operators during diagnostic catheterization and coronary angioplasty. Cathet Cardiovasc Diagn 1997;40:348-51.

7.- Otras publicaciones del autor relacionadas con el tema de la tesis

- **Fernández, J.M.** and Guibelalde, E. *Physical evaluation of recent Kodak films for mammography*. Br J Radiol 1993;66:828-832.
- Guibelalde, E.; **Fernández, J.M.**; Vañó, E.; Llorca, A.L. and Ruiz, M.J. *Image quality and patient dose for different screen-film combinations*. Br J Radiol 1994;67:166-173.
- Vañó, E.; González, L.; Guibelalde, E.; **Fernández, J.M.**; Calzado, A. and Ruiz, M.J. *Some results from a diagnostic radiology optimization programme in the Madrid area*. Radiat Prot Dosim 1995;57(1-4):289-292.
- Vañó, E.; González, L.; **Fernández, J.M.** and Guibelalde, E. *Patient Dose Values in Interventional Radiology*. Br J Radiol 1995;68:1215-1220.
- Vañó, E.; Oliete, S.; González, L.; Guibelalde, E.; Velasco, A. and **Fernández, J.M.** *Image quality and dose in lumbar spine examinations: results of a 5 year quality control programme following the European quality criteria trial*. Br J Radiol 1995;68:1332-1335.
- Vañó, E.; Guibelalde, E.; Morillo, A.; Alvarez-Pedrosa, C.S. and **Fernandez, J.M.** *Evaluation of the European Image quality criteria for chest examinations*. Br J Radiol 1995;68:1349-1355.
- Guibelalde, E.; Morillo, A.; **Fernández, J.M.** and Vañó, E. *Use of the European image quality criteria for screen-film comparison: application for asymmetric systems*. Br J Radiol 1996;69:64-69.
- Ruíz, M.J.; Vañó, E.; González, L.; **Fernández, J.M.** *Dose-area product*

values in frequently performed complex paediatric radiology examinations.
Br J Radiol 1996;69:160-164.

- **Fernández, J.M.;** Vañó, E. and Guibelalde, E. *Patient doses in hysterosalpingography.* Br J Radiol 1996;69:751-754.
- Vañó, E.; Guibelalde, E.; **Fernández, J.M.;** González, L. and Ten, J.I. *Patient dosimetry in interventional radiology using slow films.* Br J Radiol 1997;70:195-200.
- Vañó, E.; González, L.; Guibelalde, E.; **Fernández, J.M.;** and Ten, J.I. *Radiation exposure to medical staff in interventional and cardiac radiology.* Br J Radiol 1998;71:954-960.
- Vañó, E.; **Fernandez, J.M.;** Gracia, A.; Guibelalde, E. and Gonzalez, L. *Routine quality control in digital versus analog radiology.* Physica Medica 1999;XV–4:319-321.
- Vañó, E.; Gonzalez, L.; Ten, J.I.; **Fernandez, J.M.;** Guibelalde, E. and Macaya, C. *Skin dose and dose-area product values for interventional cardiology procedures.* Br J Radiol 2001;74:48-55.
- Vañó, E.; **Fernandez, J.M.;** Ten, J.I.; Guibelalde, E.; Gonzalez, L. and Pedrosa, C. *Real-Time Measurement and Audit of Radiation Dose to Patients Undergoing Computed Radiography.* Radiology 2002;225:283-288.
- Vañó, E.; Prieto, C.; **Fernandez, J.M.;** Gonzalez, L.; Sabate, M. and Galvan, C. *Skin dose and dose-area product values in patients undergoing intracoronary brachytherapy.* Br J Radiol 2003;76:32-38.
- Guibelalde, E.; Vañó, E.; Gonzalez, L.; Prieto, C.; **Fernandez, J.M.** and Ten, J.I. *Practical aspects for the evaluation of skin doses in interventional cardiology using a new slow film.* Br J Radiol 2003;76:332-336.

- Chevalier, M.; Morán, P.; Ten, J.I.; **Fernández Soto, J.M.**; Cepeda, T. and Vañó, E. *Patient dose in digital mammography*. Med Phys 2004;31(9):2471-2479.
- Vano E, Archer B, Faulkner K, Geiger B, Loose R, Bergh B, Busch HP, **Fernandez JM**, Gagne R, Rosenstein M, Sharp C, Wucherer M. International Commission on Radiological Protection. Managing Patient Dose in Digital Radiology. ICRP Publication 93. Ann. ICRP 34(1). 2004.
- Moran P, Chevalier M, Ten JI, **Fernandez Soto JM**, Vano E. *A survey of patient dose and clinical factors in a full-field digital mammography system*. Radiat Prot Dosim 2005;114(1-3):375-9.
- Vano E, Gonzalez L, Guibelalde E, Aviles P, **Fernandez JM**, Prieto C, Galvan C. *Evaluation of risk of deterministic effects in fluoroscopically guided procedures*. Radiat Prot Dosim 2005;117(1-3):190-4.
- Vano E, **Fernandez JM**, Ten JI, Gonzalez L, Guibelalde E, Prieto C. *Patient dosimetry and image quality in digital radiology from online audit of the X-ray system*. Radiat Prot Dosim 2005;117(1-3):199-203.
- Vano E, Gonzalez L, **Fernandez JM**, Prieto C, Guibelalde E. *Influence of patient thickness and operation modes on occupational and patient radiation doses in interventional cardiology*. Radiat Prot Dosim. 2006;118(3):325-30.
- Vano E, Gonzalez L, **Fernandez JM**, Alfonso F, Macaya C. *Occupational radiation doses in interventional cardiology: a 15-year follow-up*. Br J Radiol 2006;79(941):383-8.
- Prieto C, Vano E, **Fernandez JM**, Galvan C, Sabate M, Gonzalez L, Martinez D. *Six years experience in intracoronary brachytherapy procedures: patient doses from fluoroscopy*. Br J Radiol 2006;79(945):730-

3.

- Vano E, **Fernandez JM**. *Patient dose management in digital radiography*. Biomed Imaging Interv J 2007;3(2):e26.
- Simon R, Vano E, Prieto C, **Fernandez JM**, Ordiales JM and Martinez D. *Criteria to optimise a dynamic flat detector system used for interventional radiology*. Radiat Prot Dosim 2008;129(1-3):261-4.
- Vano E, Segarra A, **Fernandez JM**, Ordiales JM, Simon R, Gallego JJ, Del Cerro J, Casasola E, Verdu JF, Ballester T, Sotil J, Aspiazu A, Garcia MA, Moreno F, Carreras F, Canis M, Soler MM, Palmero J, Ciudad J, Diaz F, Hernandez J, Gonzalez M, Rosales P. A pilot experience launching a national dose protocol for vascular and interventional radiology. Radiat Prot Dosim 2008;129(1-3):46-9.
- Tsapaki V, Vano E, Muavrikou I, Nueofotistou V, Gallego JJ, **Fernandez JM**, Santos E, Mendez J. *Comparison of patient dose in two-dimensional carotid arteriography and three-dimensional rotational angiography*. Cardiovasc Intervent Radiol 2008;31(3):477-82
- Sanchez Jacob R, Vano-Galvan E, Vano E, Gomez Ruiz N, **Fernandez Soto JM**, Martinez Barrio D, Prieto C. *Optimising the Use of Computed Radiography in Pediatric Chest Imaging*. J Digit Imaging 2009;22(2):104-13.
- Vano E, Sanchez R, **Fernandez JM**, Gallego JJ, Verdu JF, de Garay MG, Aspiazu A, Segarra A, Hernandez MT, Canis M, Diaz F, Moreno F, Palmero J. *Patient dose reference levels for interventional radiology: a national approach*. Cardiovasc Intervent Radiol 2009;32(1):19-24.
- Vano E, Sanchez R, **Fernandez JM**, Rosales F, Garcia MA, Sotil J, Hernandez J, Carrera F, Ciudad J, Soler MM, Ballester T. Importance of dose settings in the x-ray systems used for interventional radiology: a

national survey. *Cardiovasc Intervent Radiol* 2009;32(1):121-6.

- Vano E, Ubeda C, **Fernandez JM**, Sanchez RM, Prieto C. *Dose assessment during the commissioning of flat detector imaging systems for cardiology*. *Radiat Prot Dosim* 2009;136(1):30-7.
- Sanchez R, Vano E, **Fernandez JM**, Sotil J, Carrera F, Armas J, Rosales F, Pifarre X, Escaned J, Angel J, Diaz JF, Bosa F, Saez JR, Goicolea J. *A national programme for patient and staff dose monitoring in interventional cardiology*. *Radiat Prot Dosim* 2011;147(1-2):57-61.
- Sanchez R, Vano E, **Fernandez JM**, Machado A, Roas N. *Visual and numerical methods to measure patient skin doses in interventional procedures using radiochromic XR-RV2 films*. *Radiat Prot Dosim* 2011;147(1-2):94-8.
- Sanchez R, Vano E, Ubeda C, **Fernandez JM**, Balter S, Hoornaert B. *Influence of Image Metrics When Assessing Image Quality from a Test Object in Cardiac X-ray Systems: Part II*. *J Digit Imaging* 2012. [Epub ahead of print].
- Vano E, Escaned J, Vano-Galvan S, **Fernandez JM**, Galvan C. *Importance of a Patient Dosimetry and Clinical Follow-up Program in the Detection of Radiodermatitis After Long Percutaneous Coronary Interventions*. *Cardiovasc Intervent Radiol* 2012. [Epub ahead of print].

8.- Trabajo I

Transition from Screen-Film to Digital Radiography: Evolution of Patient Radiation Doses at Projection Radiography¹

Eliseo Vaño, PhD
 José Miguel Fernández, MSc
 José Ignacio Ten, MSc
 Carlos Prieto, MSc
 Luciano González, PhD
 Ricardo Rodríguez, MD, PhD
 Hugo de Las Heras, MSc

Purpose:

To retrospectively evaluate patient radiation doses in projection radiography after the transition to computed radiography (CR) in the authors' hospital.

Materials and Methods:

The hospital's ethical committee approved the study and waived informed consent. In 2001, a dose reduction initiative was implemented, which involved collecting radiographic parameters, calculating patient entrance doses, and monitoring changes with an online computer, and a training program for radiographers was conducted. A database with 204 660 patient dose values was used to compute changes in patient doses over time. Sample sizes ranged from 1800 to 23 000 examinations. Doses were compared with European and American reference values. Kruskal-Wallis and Mann-Whitney tests were used for statistical analysis.

Results:

Median values for patient entrance doses increased 40%–103% after implementation of CR. Initial increases were corrected during the 1st year, and additional dose decreases were achieved after the dose reduction initiative was launched. At present, doses range between 15% and 38% of the European diagnostic reference levels established for screen-film radiography and between 28% and 41% of the reference values recommended by the American Association of Physicists in Medicine, representing an effective 20%–50% reduction in the initial values for CR.

Conclusion:

Though patient doses can increase considerably during the transition from conventional screen-film radiography to CR, dose management programs, including specific training of radiographers and patient dose audits, allow for reductions of the previous values.

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¹ From the Medical Physics Service (E.V., J.M.F., C.P., H.d.L.H.) and Radiology Service (J.I.T., R.R.), San Carlos University Hospital, 28040 Madrid, Spain; and the Radiology Department, Complutense University, Madrid, Spain (E.V., J.M.F., L.G., R.R.). Received June 3, 2005; revision requested July 29; revision received June 9, 2006; accepted July 19; final version accepted September 8. Supported in part by the European Commission (DIMOND and SENTINEL programs), the Spanish Ministry for Science and Technology (project BFI2003-09434), the Spanish Ministry of Health (Directorate General of Public Health), and the Autonomous Community of Madrid (project GR/SAL/0272/2004). Address correspondence to L.G. (e-mail: luciano@med.ucm.es).

The transition from conventional screen-film to computed or digital radiography can entail an increase in patient radiation doses (1). One of the main causes for the increase is the wide dynamic range of the digital imaging systems, which allows overexposure with no adverse effect on image quality. In addition, the lack of specific training in the new digital techniques for some radiographers and the lack of well-established methods to audit patient doses in digital systems can worsen the problem of patient radiation exposure.

The International Commission on Radiological Protection (ICRP) became aware of this risk and launched several specific recommendations to manage patient doses in digital and computed radiology (1). These recommendations include appropriate training, particularly in aspects of patient dose management, revision of the diagnostic reference levels, and frequent patient dose audits. In addition, the ICRP recommended that the industry promote tools to inform radiologists, radiographers, and medical physicists about exposure parameters and the resultant patient doses.

Peters and Brennan (2) provided a warning about the likelihood of initial high doses with the use of settings rec-

ommended by manufacturers of computed radiography (CR) systems. In a retrospective analysis of 717 exposures at mobile chest examinations, they showed a substantial reduction in exposure parameters from the initial values and emphasized the need for clinicians and personnel to optimize procedures when moving to digital techniques.

In a randomized controlled trial, Weatherburn et al (3) compared the radiation doses received by patients during bedside chest radiography with those at a CR system and with those at a 400-speed screen-film system, demonstrating that the entrance surface doses were 31% higher in the CR group. The purpose of our study was to retrospectively evaluate patient radiation doses in projection radiography after the transition to CR in our hospital.

Materials and Methods

Imaging Devices

For the examination types monitored in this work, from 1999 to 2001, patients were imaged in one of three dedicated rooms, equipped with Optimus 50 generators (Philips Medical Systems, Best, the Netherlands) and devoted to general projection radiography, in a university hospital with 965 beds and 336 840 radiologic examinations in 2004. The rooms are linked to a personal computer through patient data organizer systems (Philips). All three radiographic systems have automatic exposure control devices, properly adjusted by the technical service of the manufacturer for screen-film or equivalent CR systems of nominal speed class 400, and are submitted to periodic quality control (QC) by the medical physics service of the hospital. Measured half-value layer values at 80 kVp were between 3.9 and 4 mm Al (typical values for these units). The same rooms, equipped with other radiography units, were used through 1997 and 1998 for conventional screen-film radiography, also adjusted to a speed class of 400.

Since 1999, photostimulable phosphor plates (models MD10, MD30, and MD40; Agfa-Gevaert, Mortsel, Belgium) have been used for digital imaging with several CR sys-

tems (ADC Compact; Agfa-Gevaert) and their corresponding workstations. Though improvements in image quality may have been noted when plates MD30 or MD40 are used instead of model MD10, exposure settings were not changed, because no specific recommendation was given by the manufacturer. Moreover, older and newer plates were used during the same time period for every room and every examination type.

For each type of radiographic examination, the imaging parameters (kilovolt peak, focal spot size, automatic exposure control chamber) archived in the radiography system and set in accordance with the European guidelines on quality criteria for diagnostic radiography (4), are automatically selected for a source-to-skin distance (SSD) also specified in the guidelines. The radiographer in charge may sometimes change the radiographic technique by using the manual mode instead of automatic exposure control and choosing different SSD, kilovolt peak, and milliamperes-second settings according to individual patient characteristics or the radiographer's own preferences.

A computer program based on Visual Basic (Microsoft, Redmond, Wash), designed to perform online dose monitoring and provide radiographic technique details, retrieves tube milliamperes-sec-

Advances in Knowledge

- For the examination types monitored in this study, patient doses in computed radiography were reduced to 15%–38% of the diagnostic reference levels established in the European guidelines on quality criteria for diagnostic screen-film radiography, and 28%–41% of the reference values recommended by the American Association of Physicists in Medicine, while good image quality was maintained.
- The benefits derived from the International Commission on Radiological Protection recommendations, namely, appropriate training and frequent patient dose audits, are demonstrated.

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Abbreviations:

AAPM = American Association of Physicists in Medicine

CR = computed radiography

ICRP = International Commission on Radiological Protection

QC = quality control

SSD = source-to-skin distance

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Guarantor of integrity of entire study, E.V.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; manuscript final version approval, all authors; literature research, E.V., J.M.F.; statistical analysis, E.V., H.d.L.H.; and manuscript editing, all authors

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ond, kilovolt peak, field size, and source-to-detector distance from each patient data organizer and calculates the entrance surface dose by using the x-ray tube output, which is measured periodically as part of the QC program. (The entrance surface dose, or patient entrance dose, is the absorbed dose in air at the surface of the patient in the center of the irradiated area, including the backscattered radiation from the patient.) For each examination type, a standard patient thickness is assumed for entrance dose estimation. The computer application also allows online comparison of the mean patient dose value for a recent sample with the local diagnostic reference levels in order to audit dose levels and introduce corrective action if necessary (5).

Doses monitored with the described system were obtained with undercouch or onwall stand Bucky units (Philips). In both cases, the SSDs were measured with a sensor linked to the position of the x-ray tube and reported along with the radiographic technique data. The backscatter factor was assumed to be 1.35 for all examinations, as recommended by the European guidelines document (4). Examinations obtained without Bucky units were not analyzed, because SSDs are not available from the patient data organizer in these cases.

Until 2001, the operation of the new digital systems installed in 1999 was demonstrated by the vendors in a few short information sessions. No specific training to optimize patient dose or image quality was initially included. In 2001, a training program for radiographers and radiologists was provided by the hospital's medical physics service. It was conducted over 10 hours during 1 week, and its topics included general radiation protection concepts, introduction to digital imaging, CR and flat-panel radiography, recommendations for use, and patient dose management in CR. As manual exposure techniques were sometimes used, special attention was paid to the effects of changing the technical parameters on patient dose and the optimal kilovolt peak, milliamperesecond, and SSD settings for every examination type. In addition, the QC com-

puter application was launched as an automatic routine tool for online patient dosimetry auditing and was formally integrated into the hospital QC program.

Radiologists working in the monitored rooms evaluated the quality of clinical images yearly as part of the hospital QC program, by using random samples and the anatomic criteria recommended in the European guidelines (4). According to the QC reports, images had sufficient diagnostic quality during the years reported.

Patient Data

Our ethical committee approved our study and waived informed consent. For 1997–1999 for the screen-film systems, patient dose results are scarce, because radiographic data and distances were recorded manually only as required for the QC program. At this time, a less demanding local regulation required a sample of only 10 standard-sized patients per examination type per year, and the chest and lumbar spine were chosen as target examinations for QC.

Digital imaging was put into service in 1999. Since then, relevant procedures with diagnostic reference levels published in the European guidelines (4) (ie, chest, lumbar spinal, abdominal, and pelvic examinations), as well as thoracic spinal examinations (1800–23 000 examinations per examination type), were analyzed from a sample of 204 660 adult patients in the database who were examined in the three radiography rooms.

Statistical Analysis

Because patient dose distributions are skewed—especially in digital radiology, in which high doses do not detract from image quality—the nonparametric Kruskal-Wallis test was used for analysis. After that, the Mann-Whitney test was used to identify statistically significant differences (6) in annual dose values, comparing pairs of median dose values for each examination type from consecutive years. Instead of using the usual cutoff *P* value of .05, we assumed statistical significance for differences with *P* values less than .025 to account for the fact that each year's data were included twice in the comparisons. Software (SPSS, version 12.0, 2003; SPSS, Chicago, Ill) (7) was used for the tests. Because data before 1999 were scarce, a similar statistical analysis of that period has not been possible.

Because large samples were used (between 1800 and 23 000 examinations), median and interquartile values are the best statistical descriptors. However, for comparison purposes, the mean values and standard deviations for chest examinations were also determined. Dose values were compared with those used as references by the European Commission and the American Association of Physicists in Medicine (AAPM) (4,8).

Results

During the first 3 months of 1999 (beginning of operation for the CR system),

Table 1

Mean Entrance Surface Doses before and after Installation of Digital Equipment

Examination Type*	Screen-Film Radiography (1997–1998)		Digital Radiography (1999)	
	Entrance Surface Dose (mGy)	No. of Examinations	Entrance Surface Dose (mGy)	No. of Examinations
Lumbar spine (AP)	2.9 ± 1.1	40	5.9 ± 1.9	88
Lumbar spine (lateral)	6.6 ± 2.1	40	9.5 ± 5.1	180
Chest (PA)	0.15 ± 0.06	80	0.21 ± 0.08	1200
Chest (lateral)	0.68 ± 0.22	80	1.1 ± 0.7	1100

Note.—Data are means ± standard deviations. For digital radiography, mean values are given for the first 3 months after introduction of CR in 1999. Note the 44%–103% dose increases.

* AP = anteroposterior, PA = posteroanterior.

an increase in patient doses was detected (Table 1). For the examination types monitored, significant dose reductions have been demonstrated over consecutive years since CR was implemented (Fig 1). With the dose values of 1999 used as the baseline, the Kruskal-Wallis test results showed significant global differences over the period of study (asymptotic P value $< .001$ in all

cases). Applied to pairs of consecutive years, the Mann-Whitney test results showed that significant decreases in dosage occurred between 2001 and 2002 ($P < .025$ for all examinations, except thoracic spinal examinations) (Table 2).

At present, our median entrance dose values range between 28% and 41% of the available reference values

recommended by the AAPM (8) for conventional screen-film radiography, and between 15% and 38% of those recommended by the European guidelines document (4). The maximum differences in median values for patient doses were observed between 2001 and 2002. For example, median values for posteroanterior chest examinations decreased from 0.15 to 0.09 mGy in this period (Fig 2). For chest examinations, for which we aimed to compare our results with those of other authors who assume normal distributions, the mean doses (\pm standard deviations) were $0.20 \text{ mGy} \pm 0.09$ in 1999 and $0.11 \text{ mGy} \pm 0.09$ in 2003 for posteroanterior and $0.93 \text{ mGy} \pm 0.65$ in 1999 and $0.64 \text{ mGy} \pm 0.50$ in 2003 for lateral examinations. For a considerable number of examinations, kilovolt peak settings were concentrated at two main values, and SSDs showed important variations (eg, pelvic examinations in 2003) (Fig 3).

Figure 1

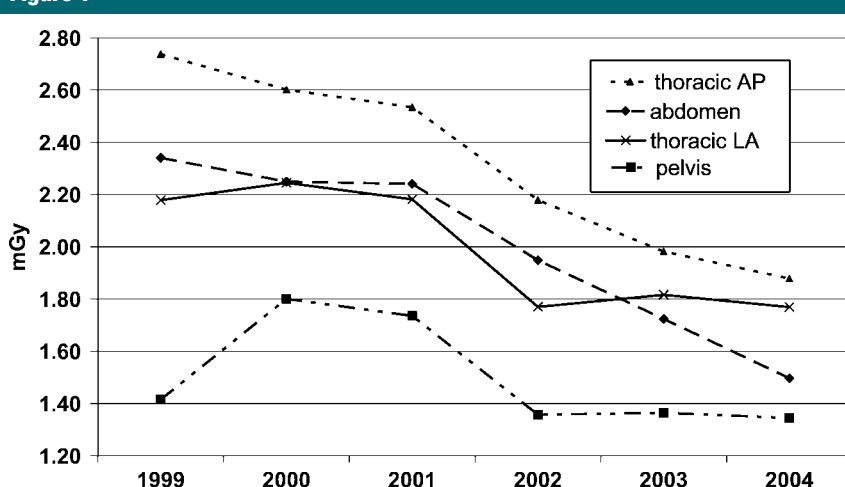


Figure 1: Graph of evolution of median values for abdominal, pelvic, and thoracic spinal examinations during period of study. After uneven results during beginning of operation of CR system in 1999, a slow decrease in median entrance dose values occurred for analyzed examinations from 1999 to 2001, with considerable decreases after training activities and routine QC operation of online audit system in 2001. AP = anteroposterior, LA = lateral.

Discussion

It is not surprising that average doses increased for some examinations when CR was introduced, as discussed and reported elsewhere (3); this increase was very apparent for chest and lumbar spinal examinations, the only examinations for which data were available before 1999. In our study, the staff had no

Table 2

Yearly Median Entrance Surface Doses after the Introduction of CR

Examination Type*	No. of Examinations	Median Entrance Skin Dose (mGy)						European Diagnostic Reference Level	AAPM Reference Value†
		1999†	2000	2001	2002	2003	2004		
Abdominal	7145	2.35	2.25 (.569)	2.24 (.369)	1.95 (.013)	1.72 (<.001)	1.50 (.022)	10	5.3
Pelvic	15 059	1.54	1.80 (<.001)	1.74 (.311)	1.36 (<.001)	1.36 (.88)	1.34 (.534)	10	...
Thoracic spinal (AP)	1859	2.74	2.60 (.915)	2.53 (.126)	2.18 (.049)	1.98 (.254)	1.88 (.619)
Thoracic spinal (lateral)	2248	2.17	2.25 (.319)	2.18 (.515)	1.77 (.003)	1.82 (.778)	1.77 (.552)
Lumbar spinal (AP)	4337	3.29	3.13 (.353)	3.09 (.492)	2.52 (.001)	2.36 (.119)	2.45 (.368)	10	5.9
Lumbar spinal (lateral)	5722	5.92	7.89 (<.001)	9.26 (.001)	7.05 (<.001)	6.43 (<.001)	8.52 (<.001)	30	...
Chest (PA)	23 224	0.18	0.17 (<.001)	0.15 (<.001)	0.09 (<.001)	0.09 (<.001)	0.10 (<.001)	0.3	0.29
Chest (lateral)	21 545	0.78	0.72 (<.001)	0.78 (<.001)	0.57 (<.001)	0.49 (<.001)	0.57 (<.001)	1.5	...

Note.—Numbers in parentheses are P values, determined with the Mann-Whitney test for comparisons of median doses with those for the previous year, for each examination type. For all examinations except anteroposterior thoracic spinal examinations, there were significant differences between doses for 2001 and 2002 ($P < .025$).

* AP = anteroposterior, PA = posteroanterior.

† Median values for 1999, excluding the first 3 months of CR.

‡ Reference values with backscatter calculated from exposure values (8) multiplied by 0.0087 mGy/mR and by 1.35.

or limited experience with digital technology, and the radiographers probably attempted to avoid noisy images by using milliamperere-second settings higher than necessary for good image quality. Use of low kilovolt peaks to increase contrast and using short SSDs were typical mistakes made by radiographers, even after the training activities held in 2001 (a worse situation [more mistakes] than that in 2003 was found in earlier years). These points were discussed in a previous dose audit of screen-film radiography and detected during a survey of patient doses (9) performed at our institution as part of a European research program. The initial increase in median yearly dose values for pelvic and anteroposterior lumbar spinal imaging from 1999 to 2001 can be explained by the inadequate selection of technical parameters for exposure.

The effect of the kilovolt peak setting on the patient entrance dose at CR has been described by Lu et al (10), who suggested the use of higher kilovolt peak settings and additional filtration of 2 mm Al at CR to reduce the patient entrance dose without compromising contrast-detail detectability. Any decrease in contrast can be offset by manipulation of the window width and level settings on soft-copy display workstations. Gray (11) recommends using a half-value layer of 3.0 mm Al at 80 kVp for diagnostic imaging. Moreover, the recently published regulations from the U.S. Food and Drug Administration (12) have increased the minimum half-value layer at 80 kVp from 2.3 to 2.9 mm Al.

Saiani et al (13) obtained doses of $0.30 \text{ mGy} \pm 0.05$ and $0.90 \text{ mGy} \pm 0.17$ for posteroanterior and lateral chest examinations, respectively, as typical entrance surface doses at chest radiography performed with a CR system (FCR 5000R CLS system; Fujifilm Medical Systems, Tokyo, Japan). These values are higher than our means and standard deviations in both 1999 and 2003.

Throughout the dose reduction program, median values decreased by 50% and 37% between 1999 and 2003 for posteroanterior and lateral chest radiography, respectively. Dose reductions

Figure 2

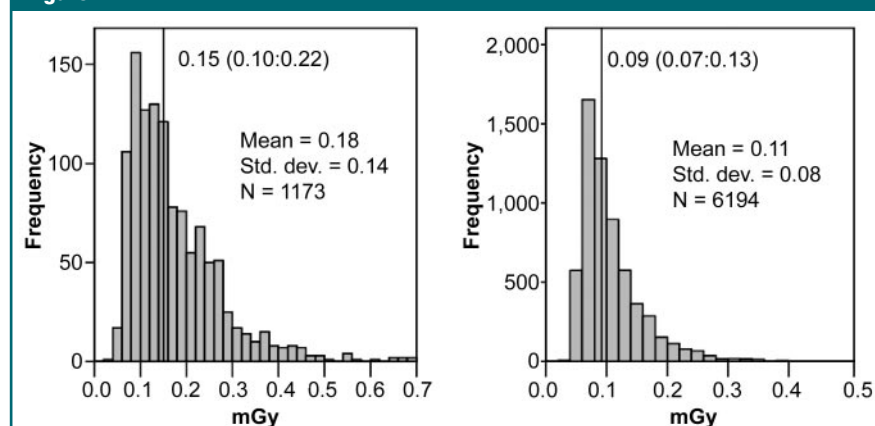


Figure 2: Histograms of dose distributions, including median (also plotted as a vertical line), first and third quartile values (in parentheses), mean, and standard deviation (*Std. dev.*) during 2001 (left) and 2002 (right) for chest imaging. Sample sizes indicate number of examinations. Furthest outlier values have not been shown.

Figure 3

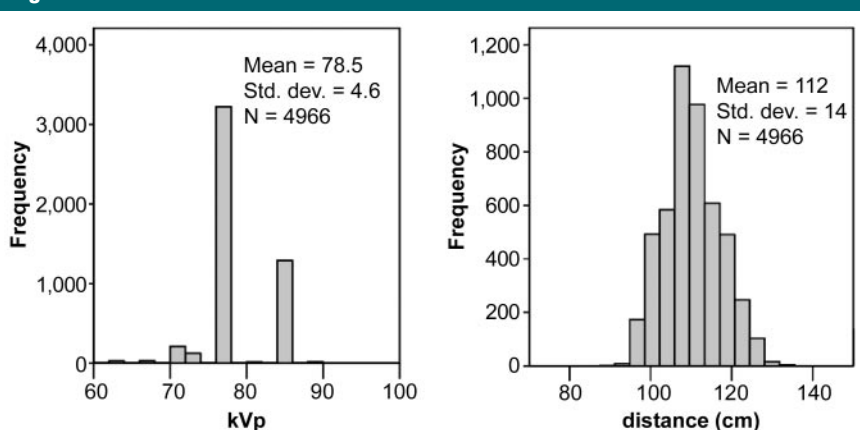


Figure 3: Kilovolt peak and focus-to-detector distance distributions for pelvic imaging in 2003, including means and standard deviations (*Std. dev.*); sample size indicates number of examinations.

could be interpreted as a benefit of training conducted by the hospital's medical physics service and application of the online patient dose audit system. From 2003 to 2004, the trend for chest and lumbar spinal examinations changed, with a slight increase in doses, suggesting a need for more training activities, especially for radiographers who joined the department after 2001. At present, the median entrance dose values at the CR examinations monitored in our department are in the range of 15%–38% of the recommended European diagnostic reference levels for conventional screen-film

radiography (4) and 28%–41% of the reference levels recommended by the AAPM in the United States (8). The on-line patient dosimetry system has proved useful in the dose reduction program.

Since the study involved examinations performed with undercouch or on-wall stand Bucky units, the results apply only to these types of examinations. Other examinations were not monitored, and this was therefore one limitation of the study. The use of a standard patient thickness for entrance dose estimation limits the overall precision of the calculated entrance surface dose values,

as it does not reflect the true skin dose for larger or smaller patients, as discussed elsewhere (5). The inaccuracy in the entrance dose should not exceed 15%, however, provided that the actual milliamperere-second used for each image is sent to the computer to calculate entrance surface dose, assuming a reasonable range in patient thicknesses of ± 5 cm around the mean for adults (children are not examined in these rooms), and given the focus-to-photostimulable-phosphor distances used at the examinations (usually 110 cm, but 180 cm for chest examinations). Such variations are unimportant, considering the sample sizes used and the fact that small and large thicknesses cancel each other out. A final weakness of the study was the fact that patients may have been imaged more than once over the course of several years, and their data would be correlated. However, this limitation is of relatively minor importance, as our sample sizes were large and our analysis concerned radiation dose per exposure and not per patient.

Although patient dose values for projection radiography can increase during the transition from conventional screen-film radiography to CR, dose management programs for digital techniques, specific training of radiographers, and frequent patient dose audits can improve practice while maintaining or reducing patient doses. Digital tech-

niques allow diagnostically adequate images to be obtained with substantially lower patient doses than used for screen-film radiography. Our study results have demonstrated the efficacy of the ICRP recommendations, namely, appropriate training and frequent patient dose audits.

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References

1. International Commission on Radiological Protection. Managing patient dose in digital radiology: a report of the International Commission on Radiological Protection. *Ann ICRP* 2004;34:1-73.
2. Peters SE, Brennan PC. Digital radiography: are the manufacturers' settings too high?—optimisation of the Kodak digital radiography system with aid of the computed radiography dose index. *Eur Radiol* 2002;12:2381-2387.
3. Weatherburn GC, Bryan S, Davies JG. Comparison of doses for bedside examinations of the chest with conventional screen-film and computed radiography: results of a randomized controlled trial. *Radiology* 2000;217:707-712.
4. European Commission. European guidelines on quality criteria for diagnostic radiographic images. Report EUR 16260. Office for the Official Publications of the European Communities. Published 1996. <ftp://ftp.cordis.lu/pub/fp5-euratom/docs/eur16260.pdf>. Accessed October 20, 2005.
5. Vano E, Fernandez JM, Ten JI, Guibelalde E, Gonzalez L, Pedrosa CS. Real-time measurement and audit of radiation dose to patients undergoing computed radiography. *Radiology* 2002;225:283-288.
6. Applegate KE, Tello R, Ying J. Hypothesis testing III: counts and medians. *Radiology* 2003;228:603-608.
7. SPSS Web site. <http://www.spss.com>. Accessed October 20, 2005.
8. Gray JE, Archer BR, Butler PF, et al. Reference values for diagnostic radiology: application and impact. *Radiology* 2005;235:354-358.
9. Vano E, Oliete S, Gonzalez L, Guibelalde E, Velasco A, Fernandez JM. Image quality and dose in lumbar spine examinations: results of a 5 year quality control program following the European quality criteria trial. *Br J Radiol* 1995;68:1332-1335.
10. Lu ZF, Nickoloff EL, So JC, Dutta AK. Comparison of computed radiography and screen-film combination using a contrast-detail phantom. *J Appl Clin Med Phys* 2003;4:91-98.
11. Gray JE. Quality control in diagnostic imaging: a quality control cookbook. Baltimore, Md: University Park Press, 1983.
12. Performance standard for diagnostic x-ray systems and their major components, 21 CFR §1020.30, §1020.31, §1020.32, and §1020.33 (2005).
13. Saiani F, Ghirardi C, Rodella CA, Feroldi P, Chiesa A. Radiation dose in digital chest radiography: comparison among three technologies. *Radiol Med (Torino)* 2004;107:401-407.

9.- Trabajo II

PHYSICAL IMAGE QUALITY COMPARISON OF FOUR TYPES OF DIGITAL DETECTOR FOR CHEST RADIOLOGY

J. M. Fernandez^{1,2,*}, J. M. Ordiales¹, E. Guibelalde², C. Prieto¹ and E. Vano^{1,2}

¹Medical Physics Department, San Carlos University Hospital, 28040 Madrid, Spain

²Radiology Department, Complutense University, 28040 Madrid, Spain

Image quality for similar exposure conditions has been compared for two computed radiography (CR) systems (needle-based and conventional storage phosphor) and two flat-panel (DR) systems from different manufacturers mainly devoted to chest radiology. Image quality was assessed with a contrast-detail object and acrylic material to simulate clinical conditions. Specific image evaluation software was used to measure the contrast and obtain an image quality figure. Phantom and detector incident air kerma were measured for all images. Image quality differences were significant, and in the range of 100–300 μGy (phantom incident air kerma) the needle-based CR system and one of the DR systems show similar image quality and they are quite superior when compared with the conventional CR system.

INTRODUCTION

The purpose of this paper is to compare the performance of four digital radiology systems devoted to chest radiology in terms of image quality versus patient dose and to evaluate the possible optimisation of the image quality. One of the computed radiography (CR) systems evaluated is a new device where the storage-phosphor is needle-based with a newly developed specific digitiser (line-scanner) for its reading. It enables reduction of patient doses while maintaining enough diagnostic image quality or improved image quality in selected examinations.

In any medical use of ionising radiation, to obtain enough diagnostic information should be the first priority, but patient radiation doses are of special concern due to the probability to produce stochastic effects. Especially in digital systems, the quality of the images can be improved by increasing patient doses. But the quality of the images should not be better than necessary. The goal should be just enough quality for diagnosis, not the best quality.

The implementation of digital radiography techniques can entail an increase in patient radiation doses^(1,2), if a strict quality control (QC) programme is not launched in parallel. Patient dosimetry and image quality evaluation are basic aspects of any QC programme in diagnostic radiology. Image quality must be adequate for diagnosis and obtained with reasonable patient doses. No dose limit applies to medical exposure of patients, but diagnostic reference levels (DRLs) for broadly defined types of equipment have been proposed by the International Commission on Radiological Protection^(3,4). DRLs are defined as dose levels in medical radiology diagnostic practices for typical examinations of groups

of standard-sized patients or standard phantoms. Specific legislation and guidelines requiring Member States to adopt such DRLs have been published in the European Union (EU)^(5,6).

Before allowing the application of new digital radiology systems with their possible advantages for patients in clinical practice, a physical comparison is necessary to identify the radiological techniques in which these possible dose reductions or image quality improvements are expectable. The way selected to reach this goal has been to compare image quality for similar exposures with a needle-based CR system, a conventional CR system and two flat-panel systems.

MATERIALS AND METHODS

The evaluation has been carried out in a large university hospital with about 1000 beds, and a full digital diagnostic department where more than 350 000 radiological procedures are performed annually. Four digital systems devoted to chest imaging have been compared:

A conventional AGFA CR Compact Plus system with plates AGFA MD40 (CR1) with a scanning resolution of 10 pixels/mm, and a matrix size of 3480×4248 (35×43 cm).

A needle-based AGFA DXS system with storage phosphor plates AGFA CR HD 5.0 (CR2). Needle-based detector technology uses a crystal phosphor that allows higher packing density and layer thickness than that offered by powder phosphor, reduces light spread and increases sharpness. The detector has scan-head line-to-line technology with a scanning resolution equal to $50 \mu\text{m}$ (20 pixel/mm).

The first flat-panel (DR) unit, installed at this centre in 2001, was a General Electric Revolution XQ/i (DR1) with a one-piece amorphous silicon

*Corresponding author: jfernandez.hcsc@salud.madrid.org

panel with caesium iodide scintillator, a matrix size of 1936×1786 pixel (200 μm of pixel size) in an active detector area of 41×41 cm.

The most recently installed DR unit, a Philips Digital Diagnost (DR2) with a detector of amorphous silicon and caesium iodide scintillator, a matrix size of 3000×3000 pixel (143 μm of pixel size) in an active detector area of 43×43 cm.

To evaluate image quality, a specific contrast-detail phantom for digital radiology (Artinis CDRAD type 2.0, www.artinis.com) was used. To simulate the attenuation and scatter for clinical conditions, a 20 cm thickness acrylic phantom was used. Four series of images were obtained with the same tube voltage (125 kVp) at eight exposure levels (0.6, 1, 2, 4, 8, 16, 32 and 64 mAs) to cover a wide exposure range, with values much higher and much lower than the usual setting of the automatic exposure control for chest examinations.

To avoid the dependence on the observer in the evaluation and scoring of the image quality, image evaluation software (CDRAD Analyser Version 1.1, Artinis Medical Systems BV, www.artinis.com) developed specifically for the test object was used to determine the threshold contrast of the 15 circular holes with diameters ranging from 0.3 to 8.0 mm that compose the test object. To quantify image quality, the inverse of image quality figure (IQFi) method has been used⁽⁷⁾.

$$\text{IQFi} = \frac{100}{\sum_{i=1}^{15} C_i \times D_{i,\text{th}}}$$

$\text{IQFi} = 100 / \sum_{i=1}^{15} C_i \times D_{i,\text{th}}$ where $D_{i,\text{th}}$ denotes the threshold diameter in contrast-column, i and C_i denotes the correctly identified contrast values. Norrman *et al.*⁽⁸⁾ evaluated the IQF method and it was shown that the computer programme produces IQFs with small variations and there is a strong linear statistical relation between the computerised evaluation and the evaluation performed by human observers ($R^2 = 0.98$). This method offers a fast and easy way of conducting image quality evaluations. Pascoal *et al.*⁽⁹⁾ concluded that the software proved more sensitive and was able to detect smaller low-contrast variations. The observer's performance was superior to the software's in the detection of smaller details. Both scoring methods showed frequent agreement in the detection of image quality variations resulting from changes in kilovolt peak (kVp) and kerma, which indicates the potential to use the software CDRAD analyser for the assessment of relative image quality.

To measure phantom and detector surface air kerma, a solid-state-based quality control device (Unfors Xi with detector Unfors 8202030-B Xi R/F & MAM Detector, www.unfors.com) was used.

This detector provided for each exposure the dose, exposure time, measured kVp and half value layer.

X-ray exposures for CR systems (CR1 and CR2) were made in a Philips Optimus 50 system, that is under a quality assurance programme with exposure reproducibility better than 2% and kVp accuracy better than 5%. The half value layer in this tube is 4.9 mm Al at 125 kVp. Focus to phantom surface distance was 154 cm, and the distance focus to image detector was 176 cm.

The flat-panel systems (DR1 and DR2) have their own tube and generator, but they are under the same quality assurance programme as the other X-ray systems. All modalities are maintained by their respective manufacturers and follow their own preventive maintenance programmes. The half value layer for the DR1 tube is 4.7 mm Al at 125 kVp. The distance from focus to phantom surface is 161 cm, and the distance from focus to image detector is 182 cm. The half value layer for the DR2 tube was 6.7 mm Al at 125 kVp. The distance from focus to phantom surface was 165 cm, and the distance from focus to image detector was 186 cm.

The differences in focus to phantom surface distance in the four systems are due to the configuration of each room for chest examinations. All images have been made in bucky with grid and were processed with the default parameters configured in each modality for chest examinations.

RESULTS AND DISCUSSION

Table 1 shows phantom incident air kerma (in μGy), detector incident air kerma with grid (in μGy) and the IQFi for increasing values of milliamperes.

Figure 1 presents IQFi versus phantom incident air kerma (μGy) for the four systems. To make an easier comparison, doses have been represented in a logarithmic scale, where the area of interest for chest examinations is at the intermediate dose values. Values under 50 μGy cannot be too representative due to excessive noise in the images. The reference value for chest PA examination is 0.3 mGy⁽¹⁰⁾ and usual values for this examination in our centre are around 0.1 mGy. In this range of values, the CR2 and DR2 systems show better IQFi than the CR1 and DR1 systems, with a trend to better results for DR2 for lower doses. Several authors^(11–14) presented results indicating that DR systems demonstrate the highest potential for high image quality when reducing the exposure dose. Depending on the system generation, the storage phosphor systems also show an improved image quality, but the possibility of a dose reduction is limited in comparison with the flat-panel detector system. Korner *et al.*⁽¹⁵⁾ compared powder- and needle-structured storage phosphor systems and concluded that images obtained with a needle image plate/line scanner

COMPARISON OF FOUR TYPES OF DIGITAL DETECTOR

Table 1. Inverse of Image Quality Figure (IQFi), Phantom Incident Air Kerma (PIAK) and Detector Incident Air Kerma (DIAK) for increasing values of mAs.

mAs	CR1			CR2			DR1			DR2		
	PIAK ^a	DIAK ^a	IQFi	PIAK ^a	DIAK ^a	IQFi	PIAK ^a	DIAK ^a	IQFi	PIAK ^a	DIAK ^a	IQFi
0.6	31.6	0.92	0.56	31.6	0.92	0.51	32.7	1.16	0.53	18.2	0.83	0.95
1.0	49.9	1.65	0.72	49.9	1.65	0.66	50.3	1.86	0.76	30.5	1.53	1.02
2.0	100.8	3.58	1.06	100.8	3.58	1.58	98.3	3.72	1.38	59.7	3.10	1.53
4.0	199.9	7.43	1.46	199.9	7.43	2.47	195.0	7.53	1.67	121.2	6.26	2.16
8.0	401.7	15.19	2.03	401.7	15.19	2.89	388.2	14.99	2.29	241.1	12.56	2.36
16.0	803.2	30.72	2.30	803.2	30.72	4.04	781.2	29.88	2.76	483.5	25.63	2.65
32.0	1608.0	62.01	2.74	1608.0	62.01	5.58	1570.0	60.20	3.05	968.8	51.04	4.00
63.0	3172.0	121.80	2.88	3172.0	121.80	6.59	3073.0	117.40	3.87	1907.0	100.00	5.13

^aIncident Air Kerma expressed in μGy .

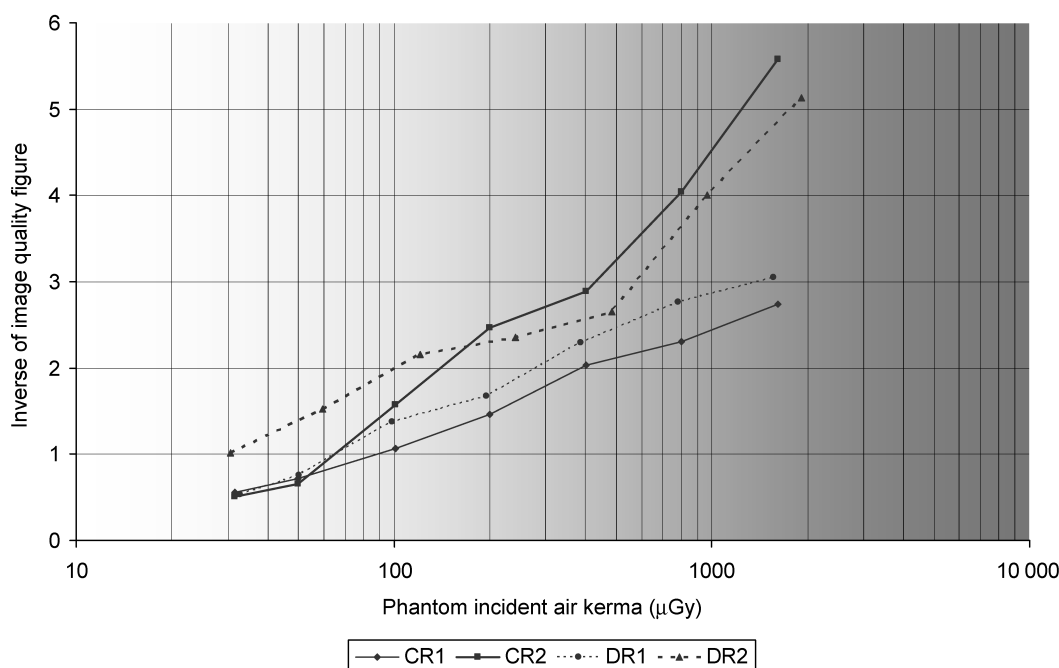


Figure 1. Comparison of the Inverse of Image Quality Figure (IQFi) vs. Phantom Incident Air Kerma (PIAK) for the four systems evaluated. Higher value of IQFi means better image quality.

provide superior low-contrast performance when compared with the images obtained with powder image plate/flying-spot scanners. All these results are compatible with those presented in this paper.

CONCLUSIONS

Structured CR (CR2) provides improved low-contrast detectability and a potential for dose reduction when compared with conventional CR (CR1) and in this simulation with doses over 0.2 mGy provides

even better image quality than flat-panel systems (DR1 and DR2). Although the present results suggest that these new image systems could yield image improvements or dose reductions, a clinical evaluation of image quality is necessary to confirm this hypothesis.

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REFERENCES

1. International Commission on Radiological Protection. *Managing Patient Dose in Digital Radiology*. ICRP Publication 93. Ann. ICRP 34, 1–73 (2004).
2. Vano, E., Fernandez, J. M., Ten, J. I., Prieto, C., Gonzalez, L., Rodriguez, R. and de Las Heras, H. *Transition from Screen-Film to Digital Radiography: Evolution of Patient Radiation Doses at Projection Radiography*. Radiology. **243**(2), 461–466 (2007).
3. International Commission on Radiological Protection. *Radiological Protection and Safety in Medicine*. ICRP Publication 73. Ann. ICRP 26, 1–47 (1996).
4. International Commission on Radiological Protection. *1990 recommendations of the International Commission on Radiological Protection*. ICRP Publication 60. Ann. ICRP 21, 1–201 (1991).
5. European Commission. *Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure*. Official Journal of the European Communities, L 180, 22–27 (1997).
6. European Commission. *Guidance on diagnostic reference levels (DRLs) for medical exposures*. Radiation Protection 109 Report, General Directorate Environment, Nuclear Safety and Civil Protection. Office for the Official Publications of the European Communities. L-2985 Luxembourg. (1999).
7. Thijssen, M. A. O., Thijssen, H. O. M., Merx, J. L., Lindeijer, J. M. and Bijkerk, K. R. *A definition of image quality: the image quality figure*. BIR Report 20: Optimisation of Image Quality and Patient Exposure in Diagnostic Radiology, London, (1989).
8. Norrman, E., Gardestig, M., Persliden, J. and Geijer, H. *A clinical evaluation of the image quality computer program, CoCIQ*. J. Digit. Imaging. **18**(2), 138–44 (2005).
9. Pascoal, A., Lawinski, C. P., Honey, I. and Blake, P. *Evaluation of a software package for automated quality assessment of contrast detail images—comparison with subjective visual assessment*. Phys. Med. Biol. **7**, **50**(23), 5743–5757 (2005).
10. European Commission. *European guidelines on quality criteria for diagnostic radiographic images*. Report EUR 16260. Office for the Official Publications of the European Communities. L-29 Luxembourg (1996).
11. Busch, H. P., Busch, S., Decker, C. and Schilz, C. *[Image quality and exposure dose in digital projection radiography]* Rofo. **175**(1), 32–37 (2003). In German.
12. Fischbach, F., Ricke, J., Freund, T., Werk, M., Spors, B., Baumann, C., Pech, M. J. and Felix, R. *Flat panel digital radiography compared with storage phosphor computed radiography: assessment of dose versus image quality in phantom studies*. Invest Radiol. **37**(11), 609–614 (2002).
13. Geijer, H., Beckman, K. W., Andersson, T. and Persliden, J. *Image quality vs. radiation dose for a flat-panel amorphous silicon detector: a phantom study*. Eur. Radiol. **11**(9), 1704–1709 (2001).
14. Peer, S., Neitzel, U., Giacomuzzi, S. M., Peer, R., Gassner, E., Steingruber, I. and Jaschke, W. *Comparison of low-contrast detail perception on storage phosphor radiographs and digital flat panel detector images*. IEEE Trans. Med. Imaging. **20**(3), 239–242 (2001).
15. Korner, M., Treitl, M., Schaetzing, R., Pfeifer, K. J., Reiser, M. and Wirth, S. *Depiction of low-contrast detail in digital radiography: comparison of powder- and needle-structured storage phosphor systems*. Invest Radiol. **41**(7), 593–599 (2006).

10.- Trabajo III

Paediatric entrance doses from exposure index in computed radiography

**E Vano^{1,2}, D Martinez¹, J M Fernandez^{1,2}, J M Ordiales¹, C Prieto¹,
A Floriano¹ and J I Ten³**

¹ Medical Physics Service, San Carlos University Hospital, 28040 Madrid, Spain

² Radiology Department, Complutense University, 28040 Madrid, Spain

³ Diagnostic Radiology Service, San Carlos University Hospital, 28040 Madrid, Spain

E-mail: eliseo@med.ucm.es

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Abstract

Over the last two years we have evaluated paediatric patient doses in projection radiography derived from exposure level (EL) in computed radiography (CR) in a large university hospital. Entrance surface air kerma (ESAK) for 3501 paediatric examinations was calculated from the EL, which is a dose index parameter related to the light emitted by the phosphor-stimulable plate, archived in the Digital Imaging and Communications in Medicine (DICOM) header of the images and automatically transferred to a database using custom-built dedicated software. Typical mean thicknesses for several age bands of paediatric patients was estimated to calculate ESAK from the EL values, using results of experimental measurements with phantoms for the typical x-ray beam qualities used in paediatric examinations. Mean/median ESAK values (in μGy) for the age bands of <1 year, 1–5 years, 6–10 years and 11–15 years have been obtained for chest without a bucky: 51/41, 57/34, 91/54 and 122/109; chest with a bucky (for only the last three age bands): 114/87, 129/105 and 219/170; abdomen: 119/91, 291/225, 756/600 and 1960/1508 and pelvis: 65/48, 455/314, 943/707 and 2261/1595. Sample sizes of clinical images used for the (indirect) measurements were 1724 for chest without a bucky, 799 for chest with a bucky, 337 for abdomen and 641 for pelvis. The methodology we describe could be applicable to other centres using CR as an imaging modality for paediatrics. Presently, this method is the only practical approach to automatically extract parameters contained in the DICOM header, for the calculation of patient dose values for the CR modality.

(Some figures in this article are in colour only in the electronic version)

1. Introduction

Paediatric patient dose evaluation is a critical issue in radiology, especially with regard to digital modalities. The International Commission on Radiological Protection (ICRP) advises that in digital radiology a higher dose usually means improved image quality, so a tendency results to use higher patient doses than necessary (ICRP 2004). The appropriate justification and optimization of the procedures requires radiologists to know the typical patient dose values in their respective centres.

The European Medical Exposures Directive (EC 1997) requires that patient doses be evaluated as part of the quality assurance programmes. Comparison with diagnostic reference levels is also required.

Patient doses in paediatrics are low (in general), but risk factors for stochastic effects in children are three to four times higher than in adults (ICRP 1991) and for some young patients examinations are repeated many times in a few weeks (as it is the case for premature infants).

Paediatric dosimetry is still being researched, and although there are some interesting studies on this topic (Azevedo *et al* 2006, Mohamadain *et al* 2004, Khoury and Oliveira 2003, Compagnone *et al* 2005, Montgomery and Martin 2000, NRPB 2002, Kiljunen *et al* 2007), samples are usually small and studies on digital modalities are scarce. Results on paediatric patient doses would help to set diagnostic reference levels (local or regional).

Computed radiography (CR) is still the most common digital modality in many hospitals. It is especially common for paediatric patients and for examinations performed with mobile x-ray systems. With CR, there is no physical link between the image detector (photo-stimulable phosphor plate or PSP) and the generator of the x-ray system. Thus, there is no possibility of capturing patient exposure data directly to the RIS or PACS system. Although there are x-ray generators with (proprietary) hardware interfaces, no feasible software is likely to exist in the near future.

The most prominent CR manufacturers have tried to compensate for these difficulties by auditing the exposure parameters, introducing some dose indices related to the light emitted by the phosphor plates during the digitization process. At present, an effort to standardize these dose indices has been started by the International Electrotechnical Commission but practical application will still require several more years.

We calculated entrance surface air kerma (ESAK) (also expressed in the literature as 'entrance surface dose' or ESD) from the exposure level (EL), which is a dose index parameter related to the light emitted by the PSP in CR systems, for 3501 paediatric examinations performed during the last two years in a 950-bed university hospital. This dose index parameter is archived in the DICOM header of the images and automatically transferred to a database.

2. Materials and methods

The CR imaging system used in our centre is an Agfa model MD10 (Agfa-Gevaert, Mortsels, Belgium). Readers (digitizers) are ADC compact models with their corresponding workstations. Images are processed with Agfa Multi Scale Imaging Contrast Amplification (MUSICA) software. In addition, specific dose-monitoring software, also produced by Agfa, is used to monitor ELs, calculated as the median of the logarithmic pixel values (i.e., intensity pixel level, described with signal average level) in the main histogram lobe of the image (figure 1). This value is called Log *M* or EL (Agfa 2000):

$$\text{Log } M = 2 \cdot \text{Log}(\text{SAL}) - 3.9477 \quad (1)$$

where SAL is the signal average level, proportional to the pixel values.

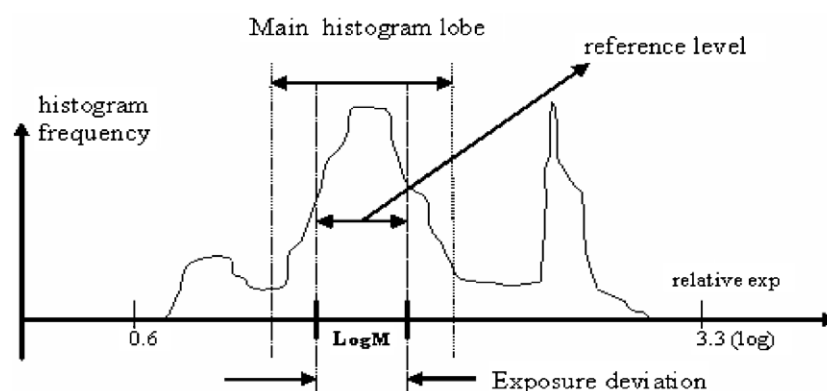


Figure 1. Graph showing how Agfa defines the exposure level ($\text{Log } M$) and the reference level (see Agfa (2000) for more details).

In figure 1, the left peak represents the lower pixel level values, i.e., related to the ‘dark’ collimated area in the image. The right peak represents the ‘bright’ direct radiation exposure areas in the image (high values of the pixel content). Both of them have to be removed in the exposure level evaluation, as they are not related to the area directly irradiated to the patient, which is otherwise related to the central peak in figure 1. EL is then evaluated using formula (1) and its value is transferred to the DICOM header of the image. The reference level in the figure is the range of values considered appropriate, according with the setting procedure of the manufacturer.

Due to the logarithmic definition of EL, an increase of 0.3 means a doubling in the dose to the PSP (SAL is proportional to dose; therefore, $\Delta \text{dose} \sim \Delta \text{SAL} \sim 10^{\Delta \text{EL}} = 10^{0.3} \approx 2$).

In our University Hospital, we use a custom-built quality control system QConLine (Vano *et al* 2005, 2007) that extracts and transfers relevant data from the DICOM headers of stored radiographs in the central PACS system to a database. From this database we have selected and analysed the data from the x-ray units used in paediatric examinations.

Experimental curves relating ESAK to EL for different kV and polymethyl methacrylate (PMMA) thicknesses to simulate typical patient sizes were obtained (with and without a bucky) following the method described in section 2.1.

2.1. Patient thickness

One of the problems in estimating the ESAK for infants is the estimation of the equivalent PMMA thickness, which depends not only on the child’s age, but also on individual characteristics (i.e., for the same age, the variability in an infant’s thickness can be substantial). Another important aspect to be taken into account is the heterogeneities in the tissues of the examined area of the patient. We adopted the factor 1.5 (Rassow *et al* 2000) to correct for these inhomogeneities only in chest PA projections, i.e., patient thickness PA/equivalent PMMA thickness = 1.5. No correction factor for the results obtained with PMMA was applied to the rest of the projections (pelvis and abdomen). Only dose results for PA or AP projections were evaluated. No lateral projections were analysed in this work.

For the estimation of mean patient thickness in the selected age group ranges <1, 1–5, 6–10 and 11–15 years for chest, pelvis and abdomen AP/PA projections, we used the NRPB-R318 methodology (NRPB 2000). The NRPB document reports four different sources of

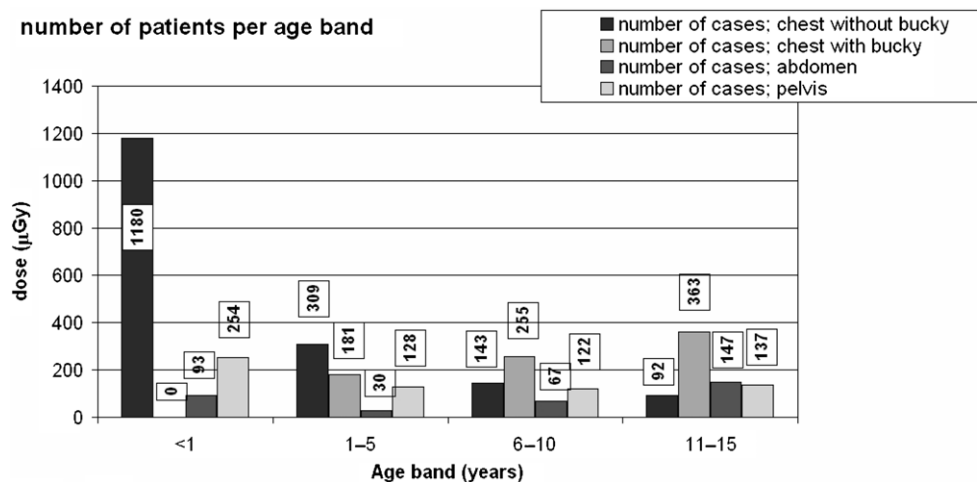


Figure 2. Total number of cases for each localization and age.

children heights, weights and thickness measurements as a function of their age to fit the weight/height ratio (w/h), i.e.,

$$\text{Thickness for one projection} = F(\text{weight/height ratio, age})$$

In our retrospective study, it was not possible to use individual w/h values because these data are not routinely introduced into the hospital information system (HIS) or the radiological information system (RIS). Thus, the NRPB sources (shown in the NRPB appendix of the quoted document) were used to estimate w/h mean values for the different age ranges. The details and results of this calculation are included in appendix A.

The total number of patients per age band and type of procedure analysed are shown in figure 2. Note that there are two groups for chest examinations (with and without a bucky). Due to the attenuation factor of the bucky, different ESAK values were obtained for the same EL for these images.

2.2. Measurements

Two x-ray systems were used to obtain the set of curves relating ESAK to EL: A GE model MPG 50 and a Philips model Optimus 50.

The qualities used were 55 kV (simulating 0–1 year exposures), 70 kV (1–5 years) and 80 kV (>5 years).

Half-value layers (HVL) at 80 kV were 3.7 mmAl and 4.0 mmAl, respectively, for both pieces of equipment. For 55 kV, measured HVL were 2.1 mmAl and 2.2 mmAl, respectively, and 2.8 mmAl for 70 kV beam quality in both machines.

The irradiation geometry to obtain the experimental curves simulates the most common clinical conditions (180 cm source–cassette distance for mural bucky geometries or 100 cm for table exposures).

Measurements of ESAK were performed with a Radcal dosimeter with a flat ionization chamber (model 2025) (Radcal, Monrovia, California), fixed upon the PMMA slabs. Dosimeter was duly calibrated.

The mAs selected for each exposure were determined in an inverse way in order to obtain appropriate values of EL. In the first approach, several mAs values were used to obtain EL

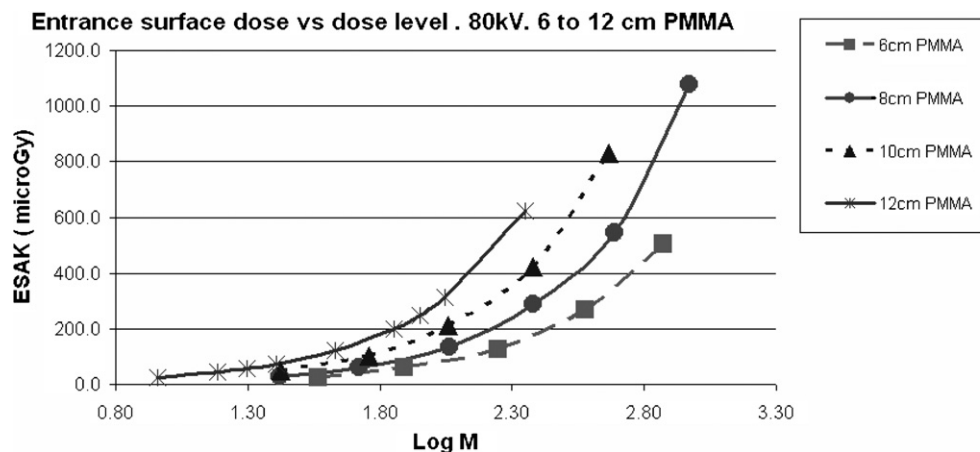


Figure 3. Example of ESAK versus Log M (exposure level, EL) values for 80 kV and different thicknesses.

values in the range 1.0–1.5 in pre-irradiations, and once found mAs were duplicated for the different measurements to increase EL by approximately 0.3 (indicating a doubling in the resulting ESAK). The imaging system used saturates the EL value in the region near EL = 3.

Although all the x-ray units (except intensive care unit mobile systems) have automatic exposure control devices, most of the paediatric examinations of this study were made with a manual selection technique.

Speed class of the plates used in measurements was the local standard one, i.e. SC = 200.

The approach used by us here differs from that described in some previous papers (Azevedo *et al* 2006, Mohamadain *et al* 2004, Khoury and Oliveira 2003, Compagnone *et al* 2005) concerning the mAs requirements. There is no need to know how the mAs were selected, as we correlate ESAK (or ESD) directly with EL (or Log M for the Agfa software). See figure 3.

The experimental curves were fitted to an exponential function with correlation values (R^2) near unity (see appendix B):

$$\text{ESAK} = A \cdot (\text{age}) \cdot \exp(B(\text{age}) \cdot \text{Log } M) \quad (2)$$

After interpolating the fitting results (table B1, appendix B) with patient mean thickness values shown in appendix A (table A2), a new fit was released, as shown in table B2.

Therefore, with the assumptions made, it becomes easy to obtain patient ESAK values if the child age and examination type (chest, pelvis or abdomen) are extracted from DICOM header, and then use is made of table B2. A physical explanation of equation (2) is derived in appendix D.

2.3. Thickness equivalent values

In this work, mean w/h values were used to derive the equivalent thickness of PMMA for different studies and age groups. A single w/h value for each age interval is not the optimal situation, as thickness variations in different patients of the same age could be large, especially in paediatrics. Nevertheless, direct individual weight and height measurements as recommended in NRPB-R318 are not included in the DICOM header in our centre, as noted

Table 1. ESAK estimation result data for chest with and without a bucky, abdomen and pelvis.

	<1 year	1–5 years	6–10 years	11–15 years
<i>Chest without a bucky</i>				
No. of cases	1180	309	143	92
Median (μGy)	40.8	33.8	53.9	108.9
3rd quartile (μGy)	67.7	65.2	100.7	150.1
Mean (μGy)	51.4	56.5	91.2	121.5
Standard deviation (μGy)	37.7	57.1	101.4	83.5
<i>Chest with a bucky</i>				
No. of cases	0	181	255	363
Median (μGy)	–	87.4	105.2	169.8
3rd quartile (μGy)	–	137.4	152.4	245.0
Mean (μGy)	–	114.3	128.9	219.1
Standard deviation (μGy)	–	96.3	80.3	170.3
<i>Abdomen</i>				
No. of cases	93	30	67	147
Median (μGy)	91.4	225.1	599.7	1507.6
3rd quartile (μGy)	141.1	355.1	927.4	2163.3
Mean (μGy)	119.0	290.8	756.0	1959.9
Standard deviation (μGy)	92.0	219.0	503.4	1760.3
<i>Pelvis</i>				
No. of cases	254	128	122	137
Median (μGy)	47.6	313.8	702.2	1595.3
3rd quartile (μGy)	90.7	636.9	1111.2	3069.7
Mean (μGy)	65.1	455.3	943.4	2261.3
Standard deviation (μGy)	57.5	405.9	825.8	1848.4

above. A detailed uncertainty estimation of this mean thickness derivation method is included in appendix B.

As we grouped the kV values according to the typical protocols of our institution (55 kV for <1 year, 70 kV for 1–5 years, 80 kV for >5 years), the kV uncertainty was estimated upon the kV accuracy during the quality controls of the x-ray systems (with deviations of no more than 1–2 kV). To be more conservative in our estimations, we supposed a maximum deviation of 5 kV (sometimes, radiographers could not use the exact kV recommended in the institution protocols for some of the exposures). As a result, the following formula (Davies *et al* 1997) was applied for uncertainty estimations (see appendix B for more details):

$$\text{ESAK}(\text{kV}) = \text{ESAK}(\text{kVo}) \cdot \left(\frac{\text{kV}}{\text{kVo}} \right)^2 \quad (3)$$

where kVo is the potential used during x-ray tube output measurements. In appendix B, a global uncertainty for ESAK calculation is detailed.

In addition, the bucky influence was evaluated as a mean dose attenuation factor for the buckys used for paediatric examinations (only chests for infants under 1 year are exposed without a bucky in our institution, typically using 55 kV). The result is roughly an attenuation dose factor (F_{bucky}) of one-third when the bucky is present. Then, expression (2) was modified to include this attenuation:

$$\text{ESAK} = \frac{1}{F_{\text{bucky}}} \cdot A(\text{age}) \cdot \exp(B(\text{age}) \cdot \text{Log } M) \quad (4)$$

3. Results

Table 1 shows the final results (mean, median, third quartile and standard deviation) for chest with/without a bucky, abdomen and pelvis. A comparison with other published data is also shown in appendix C (tables C1, C2, C3 and C4).

Median ESAK values (in μGy) (table 1) for the age bands of <1 year, 1–5 years, 6–10 years and 11–15 years are chest without a bucky: 41, 34, 54 and 109; chest with a bucky (for only the final three age bands): 87, 105 and 170; abdomen: 91, 225, 600 and 1508; and pelvis: 48, 314, 707 and 1595. Sample sizes of clinical images used for our patient dose evaluation were 1724 for chest without a bucky, 799 for chest with a bucky, 337 for abdomen and 641 for pelvis.

Mean doses range from 51 to 122 μGy for chest without a bucky, 137 to 245 μGy for chest with a bucky, 119 to 1960 μGy for abdomen and 65 to 2261 μGy for pelvis.

The standard deviations shown in table 1 implicitly take into account the uncertainty of entrance dose estimations in paediatric patients due to small thickness variations (figures B1 and B2 in appendix B).

Dose values published in table 23 of the NRPB-R318 (NRPB 2000) range approximately (mean and median values) from 300 to 1200 μGy for abdomen AP, 50 to 1500 μGy for pelvis AP and 50 to 100 μGy for AP/PA chest. Differences between NRPB values and our results are 36% for abdomen, 41% for pelvis and 71% for chest. See tables C2–C4 in appendix C for details. Wide dispersion among different sets of data is seen in tables C2, C3, C4 and table C1, which can be related not only to the uncertainties present in the dose estimation from EL values, but also to the different (local) protocol selection.

4. Conclusions

Efforts including individual and realistic w/h values in the HIS of digital radiology departments would allow their transfer to the DICOM header of the images. This would improve accuracy in paediatric patient dose evaluation when CR modality is used. Nevertheless, when patient databases are big enough, these uncertainties are compensated for and median values can be representative of the patient exposure for each age band and type of study.

This report also demonstrates the capability of the new digital imaging modalities to collect some parameters related to patient exposure automatically and to manage big sample sizes of patient dose data. These parameters have been included by the radiology industry in the DICOM header, following the ICRP recommendations (ICRP 2004) allowing the review of local diagnostic reference levels when digital systems are introduced if frequent patient dose audits are then performed. This paper offers a methodology to link some of the data contained in the DICOM header with the ESAK paediatric patient values.

This is especially relevant in paediatric radiological examinations, when one considers the paucity of existing surveys and the low number of patients usually included in the samples.

Future research may use physical modelling to obtain ESAK values from Log M , instead of mathematical fitting using experimental data as presented in this work.

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Table A1. Mean weight/height ratio as a function of child's age (obtained from NRPB-R318 report).

Age (years)	Mean w/h ratio (kg cm ⁻¹)
1	0.1304
2	0.1423
4	0.1622
5	0.1736
7	0.2014
10	0.2439
15	0.3385

Appendix A. Calculation of patient thickness values for the analysed paediatric population

All the sources quoted in the appendix of the NRPB-R318 document (NRPB 2000) were used to calculate weight/height (w/h) ratio values: data from Bohmann (1990), British Standards Institution (BSI 1990) and Freeman *et al* (1995). Mean values for 5-year-old children are shown in table A1.

Once table A1 was obtained, we fitted w/h versus age to a third grade polynomial to obtain mean w/h values for interpolating ages purposes (formula (A.1)). Finally, the mean thickness was calculated based on mean w/h values, using formulae (A.2)–(A.4) also obtained from the NRPB appendix (NRPB 2000):

$$\left(\frac{w}{h}\right)_{\text{mean, age}} = 0.000\,011 \cdot (\text{age})^3 + 0.000\,170 \cdot (\text{age})^2 + 0.009\,549 \cdot (\text{age}) + 0.121\,254 \quad (\text{A.1})$$

(age in years); $R^2 = 0.9998$.

This fit is valid for all age ranges, from 1 to 15 years.

Then we used the NRPB appendix expressions:

$$(\text{Chest AP thickness})_{\text{mean}} = 8.47 \cdot \left(\frac{w}{h}\right)_{\text{mean}} + 17.51 \cdot \left(\frac{w}{h}\right)_{\text{mean}}^{0.5} + 4.21 \quad (\text{A.2})$$

$$(\text{Abdomen AP thickness})_{\text{mean}} = -7.08 \cdot \left(\frac{w}{h}\right)_{\text{mean}} + 34.02 \cdot \left(\frac{w}{h}\right)_{\text{mean}}^{0.5} + 0.47 \quad (\text{A.3})$$

$$(\text{Pelvis AP thickness})_{\text{mean}} = -191.73 \cdot \left(\frac{w}{h}\right)_{\text{mean}}^{1.5} + 248.17 \cdot \left(\frac{w}{h}\right)_{\text{mean}} - 63.52 \cdot \left(\frac{w}{h}\right)_{\text{mean}}^{0.5} + 10.14 \quad (\text{A.4})$$

As we used the age bands recommended in several European Commission Guidelines (CEC 1996a, 1996b) and Azevedo *et al* (2006), we derived mean chest, abdomen and pelvis thicknesses for the different ages (<1, 1, 2, ..., 15 years) using formulae (A.1)–(A.4), and finally we obtained a weighted mean for each age band, taking into account the number of cases in our database for each age. For example, for chest, we used the expression

$$(\text{Mean chest AP thickness})_{\text{ab}} = \frac{\sum_i (\text{chest AP thickness})_i \cdot (\text{number of cases})_i}{\sum_i (\text{number of cases})_i} \quad (\text{A.5})$$

Table A2. Estimated mean AP/PA patient PMMA equivalent thickness.

Study	<1 year (cm)	1–5 years (cm)	6–10 years (cm)	11–15 years (cm)
Thorax AP	6.6	8.4	9.4	10.9
Abdomen AP	9.6	13	14.7	17.2
Pelvis AP	7.7	12.3	15	18.2

where i is the age in a certain age band, labelled as ‘ab’; for example, for $ab = [0, 1]$, $i = 0, 1$ years; for $ab = [2, 5]$, $i = 2, 3, 4, 5$, etc).

Grouping by age bands using this weighted method increases the number of cases, which aids statistical consistency.

Table A2 is derived in this way for the four age bands and type of study (chest, pelvis or abdomen) using equations (A.1)–(A.5).

Appendix B. ESAK measurements, fitting details and dose estimation uncertainties

The fit obtained with ESAK versus EL (see expression (2) in the main text; EL is the same as $\text{Log } M$ as used by Agfa software) gives A , B and R^2 values for each age band and PMMA thickness. Results of the fit are shown in table B1. In table B2, interpolated A and B values are calculated from mean thickness for each age band (table A2).

With respect to uncertainties, from now onward, the ESAK value derived from expression (2) means that, for a constant age (i.e., mean PMMA equivalent thickness) and EL (or $\text{Log } M$), there is one (and only one) value of ESAK.

Therefore, it could happen that, in the case of the same exposure level and age for two different children, the dose could be reported as the same ESAK for both, which is not strictly true if the thicknesses are not the same.

In figure B1, experimental measurements are made relating, for each EL, to the change in ESAK (expressed as a multiplicative factor) produced by 2 cm changes in PMMA steps (σ value in PA projection in table 3 in [4]). For the same exposure level, it is seen that dose variations ranging from 30% to 100% can occur if the level of thickness changes approximately 2 cm from the mean thickness, as estimated in figure B1. This 2 cm variation is a reasonable change value for infants of the same age, based on the measurement thickness shown in different studies (Rassow *et al* 2000).

This source of uncertainty can be estimated in the following way: for two exposures made with the same ESAK and different thickness for infants in the same age band, results would yield two different values of EL (i.e., $\text{Log } M$) in the images. As we take values of EL, age and type of exploration from the DICOM header, we suppose a unique thickness for each exploration and age band, and our algorithm would lead to two different values of ESAK, owing to the difference in EL in the two images. We have assessed this error by calculating, for the same ESAK, values of $\text{Log } M$ for the curves 2 cm from our reference thickness. We have calculated the difference in ESAK that these two values of EL gives using the reference thickness curve. An example of this is shown in figure B2.

We can estimate the error in this way: the ‘real’ dose for patient in figure B2 would be 400 μGy , if we call this value D_1 . However, our algorithm estimates 600 μGy , called D_2 . Let us also designate $(\text{Log } M)_1$ and $(\text{Log } M)_2$ as the respective exposure levels. Then,

$$\Delta D = D_2 - D_1 = A \cdot \exp[B \cdot (\text{Log } M)_2] - A \cdot \exp[B \cdot (\text{Log } M)_1] \quad (\text{B.1})$$

Table B1. Fitting values and correlation obtained from measurements on PMMA.

kV	PMMA (cm)	A (μGy)	B	R^2
55	2	0.1314	2.1777	0.9997
	4	0.1848	2.2124	0.9984
	6	0.2933	2.1997	0.9994
	8	0.4431	2.2108	0.9998
70	4	0.134	2.2401	0.9999
	6	0.1583	2.3335	0.9999
	8	0.2985	2.2285	0.9958
	10	0.3681	2.2918	0.9999
80	6	0.7918	2.2556	0.9992
	8	1.0003	2.3575	0.9990
	10	1.8542	2.2879	0.9997
	12	2.8664	2.2938	0.9999
	14	4.1607	2.3258	0.9992
	16	12.3312	2.1629	1.0000
	20	30.416	2.2499	0.9998

Table B2. Fit obtained with interpolated ESAK versus Log M curves.

kV	PMMA (cm)	Age band (years)	Study	A (μGy)	B
55	6.6	<1	Thorax AP	0.3471	2.2064
	7.7		Abdomen AP	0.405	2.2064
	9.6		Pelvis AP	0.7205	2.1718
70	8.4	1–5	Thorax AP	0.3104	2.2656
	12.3		Pelvis AP	0.6865	2.2801
	13		Abdomen AP	0.7256	2.2801
80	9.4	6–10	Thorax AP	1.4868	2.3148
	14.7		Abdomen AP	6.525	2.2948
	15		Pelvis AP	6.6581	2.2948
	10.9	11–15	Thorax AP	2.3388	2.2915
	17.2		Abdomen AP	18.9064	2.2571
	18.2		Pelvis AP	20.0057	2.2571

Table B3. Deviation in estimated ESAK with a ± 5 kV variation with respect to nominal protocols kV (measured kV variation during 2005).

kV	Correction factor factor in ESAK	Standard deviation (%)
50	0.91	9%
55	1.00	
60	1.09	
65	0.93	7%
70	1.00	
75	1.07	
75	0.94	6%
80	1.00	
85	1.06	

Multiplicative entrance surface dose factor for 70kV

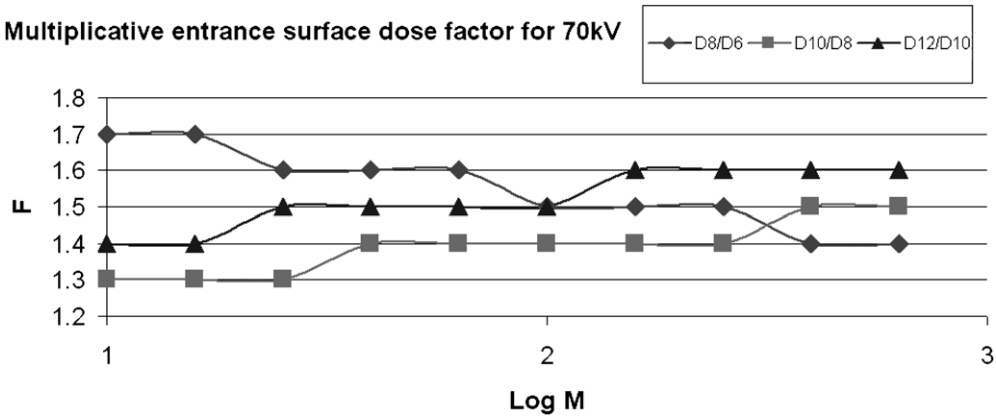


Figure B1. Measured multiplicative ESAK change factor versus $\text{Log } M$ for 2 cm changes in PMMA thickness. D_i/D_j denotes the ESAK dose ratio between the dose for i cm PMMA thickness and j cm PMMA thickness. These measured data in the figure are in good agreement with our uncertainty estimation, which shows that infant thickness is the main source of uncertainty in the present algorithm's ESAK estimation.

Entrance surface dose vs exposure level . ESD uncertainty example

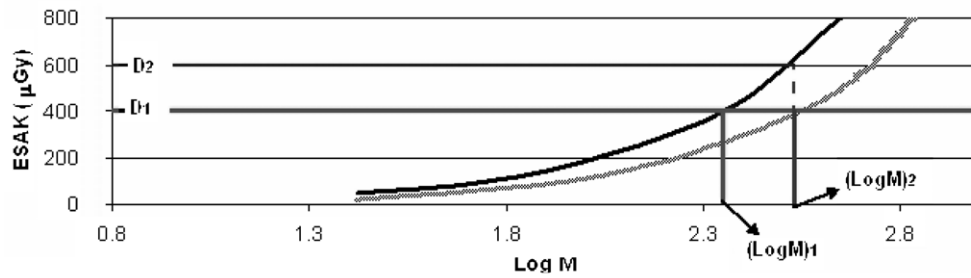


Figure B2. Uncertainty in ESAK. For same ESAK for two infants of the same age, but with different patient thickness. As $\text{Log } M$ is different for both, but only one curve is used for that age (dark), estimated (erroneous) ESAK would be around 600 μGy , instead of the 'real' value of 400 μGy .

Rearranging equation (2) gives

$$(\text{Log } M)_2 = \frac{\text{Ln}\left(\frac{D_1}{A_i}\right)}{B_i} \quad (\text{B.2})$$

where label 'i' refers to the right curve in figure B2. Substituting into (10) gives

$$\Delta D = D_2 - D_1 = A \cdot \exp\left[B \cdot \frac{\text{Ln}\left(\frac{D_1}{A_i}\right)}{B_i}\right] - D_1 \quad (\text{B.3})$$

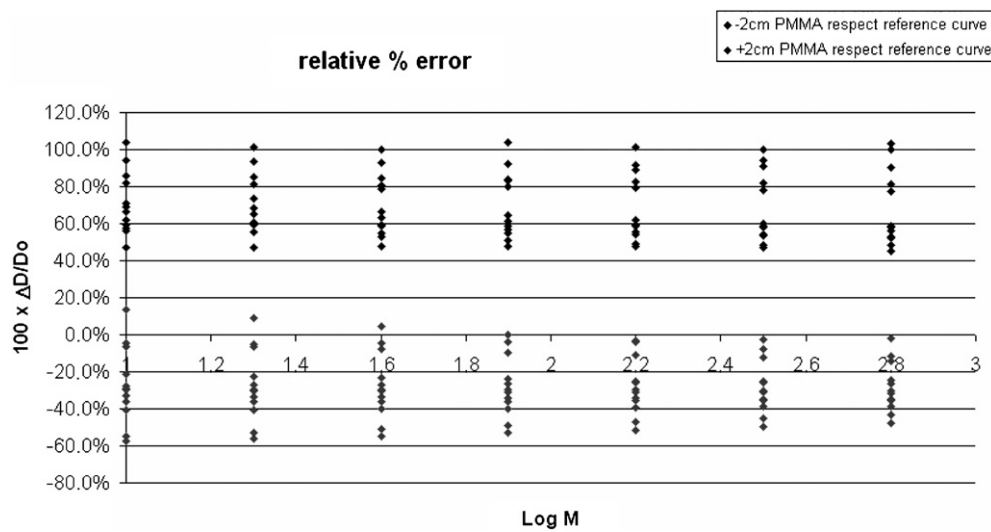


Figure B3. Estimated uncertainty in ESAK using equation (B.4). For increasing kV and thickness, there is a more pronounced uncertainty. The algorithm has more uncertainty for patients with less thickness compared to reference thickness for a given child's age.

Substituting D_1 and renormalizing to D_1 (to obtain relative error) gives

$$\frac{\Delta D}{D_1} = \frac{\exp \left[B \cdot \frac{\ln \left(\frac{A \cdot \exp(B \cdot (\text{Log } M)_1)}{A_i} \right)}{B_i} \right]}{\exp(B \cdot (\text{Log } M)_1)} - 1 \quad (\text{B.4})$$

Equation (B.4) gives the 'individual' relative uncertainty (i.e., related to one infant dose estimation) of assuming a standard curve for each age when there is a patient thickness variation. Assuming as we mentioned before a ± 2 cm equivalent PMMA thickness variation for children of same age (Rassow *et al* 2000), then using equation (B.4) we derive the estimated uncertainty as a function of $\text{Log } M$. A plot is shown in figure B3.

For kV uncertainties, 5–10% estimated uncertainties using equation (3) could be reasonable with observed year-to-year quality assurance measurements deviations in kV (as shown in table B3).

The kV error is small compared to children with thickness uncertainty (as seen in table B3), and we combine errors in a square root sum of individual quadratic uncertainties, with an estimation of 50–100% global uncertainty.

The higher the kV and patient thickness, the higher the relative error is obtained by equation (B.4) and plotted in figure B3.

Appendix C. Comparison with other published data

Table C1 shows different published paediatric reference values for chest AP projection for the age ranges <1, 1–5, 6–10. Doses present relative good agreement, except higher doses in the study from Khoury and Oliveira (2003). For comparison purposes, doses for Kiljunen *et al* (2007) data are estimated using the previous commented-upon equivalence PMMA

Table C1. Comparison values for chest AP projection ESAK with other published data.

Age band (years)	Kiljunen <i>et al</i> (2007) (μGy)	Azevedo <i>et al</i> (2006) (μGy)	Khoury and Oliveira (2003) (μGy)	Present work (2007) (μGy)	Kyriou <i>et al</i> (2000) (μGy)
<1	34	52	275	51	20
1–5	42	63	300	56	30
6–10	57	64	322	91	40
11–15	54	–	–	122	–

Table C2. NRPB-R318 reference data comparison with present work for abdomen projection.

Source	Years	Mean (μGy)	Median (μGy)	3rd quartile (μGy)
NRPB-R318 (NRPB 2000)	0	–	–	–
	1	329	340	439
	5	479	363	651
	10	756	594	846
	15	1287	1020	1578
Present work	0	–	–	–
	1	177.0	135.1	209.8
	5	328.5	254.2	401.2
	10	769.7	612.1	946.6
	15	2065.5	1594.5	2288.0
Standard deviation (%)	0	–	–	–
	1	–46.2%	–60.3%	–52.2%
	5	–31.4%	–30.0%	–38.4%
	10	1.8%	3.0%	11.9%
	15	60.5%	56.3%	45%

Table C3. NRPB-R318 reference data comparison with present work for pelvis projection.

Source	Years	Mean (μGy)	Median (μGy)	3rd quartile (μGy)
NRPB-R318 (NRPB 2000)	0	49	27	65
	1	388	336	496
	5	455	435	678
	10	713	518	892
	15	1577	1580	1910
Present work	0	–	–	–
	1	137.5	102.0	191.3
	5	483.8	331.7	673.3
	10	1000.3	803.0	998.4
	15	2568.8	2300.3	2815.3
Standard deviation (%)	0	–	–	–
	1	–64.6%	–69.7%	–61.4%
	5	8.7%	–23.7%	–0.7%
	10	40.3%	55.0%	11.9%
	15	62.9%	45.6%	47.4%

Table C4. NRPB-R318 reference data comparison with present work for chest projection.

Source	Years	Mean (μGy)	Median (μGy)	3rd quartile (μGy)
NRPB-R318 (NRPB 2000)	0	59	67	69
	1	44	35	50
	5	55	51	72
	10	88	61	128
	15	–	–	–
Present work	0	–	–	–
	1	65.0	53.2	75.4
	5	115.6	88.5	139.2
	10	146.4	124.9	179.2
	15	245.8	194.5	280.7
Standard deviation (%)	0	–	–	–
	1	47.7%	52.0%	50.8%
	5	110.2%	73.5%	93.3%
	10	66.4%	104.7%	40.0%
	15	–	–	–

thickness assumption of Rassow *et al* (2000) patient thickness PA/equivalent PMMA thickness = 1.5 and then using mean equivalent PMMA thickness for each age band shown in appendix A, table A2. Thicknesses are very similar for both studies using this method, so comparison is traceable. Values are similar in magnitude, with an exception made for the 11–15 age range between both studies, which relates 54 μGy for the Kiljunen *et al* (2007) data to 122 μGy for our study, as shown in table C1. This could be also due to uncertainties in ESAK/ESD estimations for both studies. As mentioned previously in appendix B, uncertainties are highly sensitive to patient thickness, with 30–100% ESAK variations.

Tables C2–C4 show the percentage ESAK difference between the present study and the published data in NRPB (NRPB 2000). Almost all of the deviations are between 50%, which is in concordance with the fact that protocol selection can differ slightly between our institution and the NRPB study. Moreover, there are uncertainties involved in the ESAK estimation from EL.

Appendix D. Theoretical consistency and physical derivation of equation (2)

A physical explanation of equation (2) could give self-consistency to the fitting method presented here.

A diagram of the model is shown in figure D1. E is the entrance dose to the plate in μGy .

From AAPM Report Task Group No 10 (AAPM 2006), the SAL value definition for AGFA systems is

$$\text{SAL} = 1800 \cdot \left(\frac{\text{SC}}{200} \cdot \frac{E(\mu\text{Gy})}{20} \right)^{0.5} \quad (\text{D.1})$$

SC is the speed class for the plate used. Thus, including equation (D.1) into equation (1)

$$\text{Log } M = 1.2618 + \text{Log} \left(\frac{\text{SC}}{200} \right) + \text{Log}(E) \quad (\text{D.2})$$

$$E = 10^{[\text{Log } M - 1.2618 - \text{Log}(\text{SC}/200)]} = \frac{10.945}{\text{SC}} \cdot 10^{\text{Log } M} \quad (\text{D.3})$$

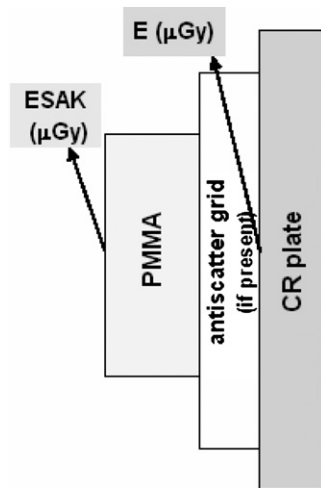


Figure D1. General scheme for physical derivation of equation (2).

Assuming an effective attenuation coefficient of μ (dependent on beam quality and material)

$$E(\mu\text{Gy}) = \text{ESAK}(\mu\text{Gy}) \cdot F_{\text{bucky}} \cdot \exp(-\mu \Delta x) \quad (\text{D.4})$$

where F_{bucky} is the antiscatter grid attenuation factor and Δx is the PMMA thickness. See figure D1.

$$\text{ESAK}(\mu\text{Gy}) = \frac{1}{F_{\text{bucky}}} \cdot \exp(\mu \Delta x) \cdot E(\mu\text{Gy}) = \frac{1}{F_{\text{bucky}}} \cdot \exp(\mu \Delta x) \cdot \frac{10.945}{\text{SC}} \cdot 10^{\text{Log } M} \quad (\text{D.5})$$

Then, using

$$10^{\text{Log } M} = \exp(\text{Ln}(10^{\text{Log } M})) = \exp(\text{Log } M \cdot \text{Ln}(10)) \quad (\text{D.6})$$

equation (D.5) becomes

$$\text{ESAK}(\mu\text{Gy}) = \left[\frac{1}{F_{\text{bucky}}} \cdot \exp(\mu \Delta x) \cdot \frac{10.945}{\text{SC}} \right] \cdot \exp(\text{Ln}(10) \cdot \text{Log } M) \quad (\text{D.7})$$

We have estimated ESAK values theoretically using equation (D7) for the same experimental set-ups as in the main text of this paper, using μ published data values in NRPB-R318 document (NRPB 2000).

The B value in equation (D.7) is equal to 2.30 (i.e. $\text{Ln}(10)$) which is in relatively good agreement with fitting values for this parameter (near this theoretical value, see table B1). A value has the uncertainty of μ theoretical input value, which could be different from experimental one. The mean absolute deviation in percentage of theoretical estimation with respect to PMMA ESAK measurements is 4.8% (1.7% in fitting to measurement model) for 55 kV, 17.5% (3.1%) for 70 kV and 23% (6%) for 80 kV. Mathematical fit to experimental values is slightly better, more pronounced for higher qualities of 70 and 80 kV, which could be related to theoretical to real (i.e. local μ values) μ values. Anyway, observed deviations are as much as 20–25% which is accordance with uncertainties.

References

- ADC Compact Dose Monitoring Software User Manual 2000 (Mortsel, Belgium: Agfa-Gevaert)
- Agfa ADC System Manual Image Processing 2000 Section 10 (Mortsel, Belgium: Agfa-Gevaert)
- American Association of Physicists in Medicine 2006 Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems *Report of AAPM Task Group 10*
- Azevedo A C P, Osibote O A and Boechat M C B 2006 Paediatric x-ray examinations in Rio de Janeiro *Phys. Med. Biol.* **51** 3723–32
- Bohmann I 1990 Ennittlung der Durchstrahlungsdurchmesser bei Säuglingen, Kindern und Jugendlichen zur Aufstellung von Belichtungswerten in der Röntgendiagnostik und Abschätzung der Organdosiswerte bei typischen Röntgenuntersuchungen, Munich. Gesellschaft für Strahlen und Umweltforschung, GSF 16 /90
- BSI—British Standards Institution 1990 Body Measurements of Boys and Girls from Birth up to 16.9 Years, BS7231, Part 1 (BSI: London)
- CEC 1996a Quality criteria for diagnostic images in paediatrics, Report EUR 16261 (Luxembourg: Office for official publications of the European Communities)
- CEC 1996b European guidelines on quality criteria for diagnostic radiographic images, Report EUR 16260 (Luxembourg: Office for official publications of the European Communities)
- Compagnone G, Pagan L and Bergamini C 2005 Local diagnostic reference levels in standard x- rays examinations *Radiat. Prot. Dosim.* **113** 54–63
- Davies M, McCallum H, White G, Brown J and Helm M 1997 Patient dose audit in diagnostic radiography using custom designed software *Radiography* **3** 17–25
- European Commission 1997 Council directive 97/43/EURATOM on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, repealing directive 84/466/EURATOM *Off. J. Eur. Comm. L* **180** 22–7
- Freeman J V, Cole T J, Chinn S, Jones P R, White E M and Preece M A 1995 *Arch. Dis. Child.* **73** 17–24 Cross sectional stature and weight reference curves for the UK, 1990
- ICRP 1991 1990 Recommendations of the International Commission on Radiological Protection *Ann. ICRP* **21** 1–201
- ICRP 2004 Managing patient dose in digital radiology. ICRP Publication 93 *Ann. ICRP* **34** 1–73
- Khoury H J and Oliveira M 2003 Influencia do procedimento radiografico na dose de entrada na pele de pacientes em radiologia pediátrica *Radiol. Brasileira* **36** 105–9
- Kiljunen T, Jarvinen H and Savolainen S 2007 Diagnostic reference levels for thorax x-ray examinations of paediatric patients *Br. J. Radiol.* **80** 452–9
- Kyriou J C, Newey V and Fitzgerald M C 2000 *Patient Doses in Diagnostic Radiology at the Touch of a Button* (London: The Radiological Protection Center, St George's Hospital)
- Mohamadain K E M, da Rosa L A R, Azevedo A C P, Guebel M R N, Boechat M C B and Habani F 2004 Dose evaluation for paediatric chest x-ray examinations in Brazil and Sudan: low doses and reliable examinations can be achieved in developing countries *Phys. Med. Biol.* **49** 1017–31
- Montgomery A and Martin C J 2000 A study of the application of paediatric reference levels *Br. J. Radiol.* **73** 1083–90
- National Radiological Protection Board (NRPB) 2000 Reference doses and patient size in paediatric radiology (Table 23). *Radiology* NRPB-R318 (Chilton: NRPB)
- National Radiological Protection Board (NRPB) 2002 Doses to Patients from Medical X-Ray Examinations in the UK—2000 Review. NRPB-w14 (Chilton: NRPB)
- Rassow J, Schmaltz A A, Hentrich F and Streffer C 2000 Effective doses to patients from paediatric cardiac catheterization *Br. J. Radiol.* **73** 172–83
- Vano E, Fernandez J M, Ten J I, Gonzalez L, Guibelalde E and Prieto C 2005 Patient dosimetry and image quality in digital radiology from online audit of the x-ray system *Radiat. Prot. Dosim.* **117** 199–203
- Vano E, Fernandez J M, Ten J I, Prieto C, Gonzalez L, Rodriguez R and de Las Heras H 2007 Transition from screen-film to digital radiography: evolution of patient radiation doses at projection radiography *Radiology* **243** 461–6

11.- Trabajo IV

Image Retake Analysis in Digital Radiography Using DICOM Header Information

C. Prieto,¹ E. Vano,^{1,2} J. I. Ten,³ J. M. Fernandez,¹ A. I. Iñiguez,³ N. Arevalo,³ A. Litcheva,³ E. Crespo,³ A. Floriano,¹ and D. Martinez¹

A methodology to automatically detect potential retakes in digital imaging, using the Digital Imaging and Communications in Medicine (DICOM) header information, is presented. In our hospital, neither the computed radiography workstations nor the picture archiving and communication system itself are designed to support reject analysis. A system called QCOOnline, initially developed to help in the management of images and patient doses in a digital radiology department, has been used to identify those images with the same patient identification number, same modality, description, projection, date, cassette orientation, and image comments. The pilot experience lead to 6.6% and 1.9% repetition rates for abdomen and chest images. A thorough analysis has shown that the real repetitions were 3.3% and 0.9% for abdomen and chest images being the main cause of the discrepancy being the wrong image identification. The presented methodology to automatically detect potential retakes in digital imaging using DICOM header information is feasible and allows to detect deficiencies in the department performance like wrong identifications, positioning errors, wrong radiographic technique, bad image processing, equipment malfunctions, artefacts, etc. In addition, retake images automatically collected can be used for continuous training of the staff.

KEY WORDS: Diagnostic image quality, Digital Imaging and Communications in Medicine (DICOM), image analysis

INTRODUCTION

Reject analysis is described by the Quality Assurance Working Group of the Diagnostic Methods Committee of the British Institute of Radiology as ‘the critical evaluation of radiographs which are used as part of the imaging service but do not play a useful part in the diagnostic

process.’¹ In the digital philosophy, if we consider ‘images’ instead of ‘radiographs,’ it will refer to those images rejected as diagnostically unacceptable during imaging procedures. The total reject rate is, therefore, the number of images thrown out divided by the number of images taken within a specified period of time. It is also possible to consider the retake rate (or repeat rate), which is defined as the percentage of images that have been retaken due to error or a poor image quality.¹ The retake rate does not include those images that are diagnostically unacceptable but for different reasons are not retaken. On the other hand, some of the images that later are retaken could have acceptable diagnostic quality² but are discarded when the decision to repeat or accept an image as diagnostic is made exclusively by a not experienced or well-trained radiographer. Besides, radiographers, in most of the European Countries, are trained to recognize anatomy, not pathology.

¹From the Medical Physics Service, San Carlos University Hospital, 28040, Madrid, Spain.

²From the Radiology Department, Medicine School, Complutense University, 28040, Madrid, Spain.

³From the Radiology Service, San Carlos University Hospital, 28040, Madrid, Spain.

Correspondence to: C. Prieto, Medical Physics Service, San Carlos University Hospital, 28040 Madrid, Spain; Tel: +34-91-3303302; Fax: +34-91-3303302; e-mail: cprieto.hcsc@salud.madrid.org

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Comprehension of terminology is essential if meaningful and accurate results are to be achieved. Reject analysis in digital radiology is a challenge, and very few papers have been published on that subject. Deleting files (images) in a computer is easier than throwing films to the basket and more difficult to audit. Performing the control on the rejection rate manually has many difficulties with digital systems, but it is much more difficult to assess it automatically. In this work, we have focused on the feasibility of monitoring automatic retake rates in digital radiology departments.

The European Directive on health protection against the dangers of ionizing radiation in relation to medical exposure³ places great emphasis on the justification for radiographic exposures to ensure that patient radiation dose is minimized, and this requires greater consideration of the diagnostic efficacy of an image. Therefore, it is important to perform only clinically diagnostic examinations. Image retake analysis is a method of identifying image faults, sources of error, and in general, inappropriate practices. It is a key aspect in any quality assurance program,^{2,4-9} a basic tool to avoid unnecessary doses to patients in radiology departments,^{10,11} and a way to save time in services already suffering from a substantial scheduling backlog, improving efficiency in the use of X-ray equipment and saving space in local picture archiving and communication system (PACS). This could result eventually in better patient care.

To assure a high-quality service, service levels need to be measured within the clinical environment, and a potential measurement tool is image retake analysis. Retake analysis in a modern imaging department can be used to identify areas where improvement of service quality and cost effectiveness is needed.

The International Commission on Radiological Protection, in a recent report entitled "Managing Patient Dose in Digital Radiology,"¹² highlights the importance of retakes in the quality assurance program.

Neither the computed radiography (CR) workstations nor the PACS itself is designed in general to support reject analysis. A methodology to automatically detect potential retakes in digital imaging using the Digital Imaging and Communications in Medicine (DICOM) header information is presented.

MATERIALS AND METHODS

A system called QConline¹³ was developed as a pilot experience under the European Research Programs DIMOND and SENTINEL^{14,15} to help in the management of images and patient doses in a digital radiology department at the San Carlos University Hospital in Madrid. Currently, many digital radiography systems allow selective acceptance of images, while those that are unwanted are deleted for good. The Quality Assurance Committee of the Hospital agreed that all the images (irrespective of whether the image was considered diagnostic or not) were sent automatically to the central PACS and in parallel to a dedicated workstation located at the Medical Physics Service, where the QConline is running.

DICOM header information is automatically extracted and transferred to a data base. Relevant images can also be archived at the workstation for inspection. The initial criterion for identifying potential image retakes was that two or more images share the same patient ID (ID, identification number), same modality, description, projection, and date (see Table 1). This criterion was applied over the 3,742 abdomen and 8,636 chest CR images archived in the PACS in 3 months. A sample of the potential image retakes was evaluated by four independent radiologists to assess the criterion of the selection. After a thorough analysis of the supposed repeated images, the need for additional criteria was determined. As a result, an

Table 1. Set of Criteria Applied to Select Potential Image Retakes

Group ID	Element ID	Description
Fields used in the first assessment		
0016	0032	Patient ID
0008	0096	Modality
0008	4158	Series description
0008	0032	Study date
0024	2037	View position
0008	5122	Study description
Additional fields taken into account after the first assessment		
0018	1402	Cassette orientation
0020	4000	Image comments
0018	1404	Exposures on plate
0019	1015	IgM (exposure level)

After the first assessment, four additional fields from the DICOM header were added.

improved set of criteria was applied to the 1,893 abdomen and 4,369 chest images archived in the PACS during a month. These images were analyzed by four radiologists, and a probable cause for the retake was assigned to each one. A list of the complete set of DICOM header fields used to discriminate the potential repeated images is shown in Table 1 and an example of a the fields of a DICOM header is shown in Figure 1.

RESULTS

The initial rejection criteria led to a 15.4% retake rate in abdomen and a 4.5% retake for chest examinations. After a thorough analysis of the supposed repeated images, the need for additional criteria like orientation of the cassette (for computed radiology systems) and the number of exposures on plate was shown. For instance, both orientations of the cassette (landscape/portrait) are used in the case of large patients' abdomen imaging where a single orientation cannot cover the area to be explored, but these images were taken as repetition by the original automatic criteria of selection. Additionally, some images are reprocessed by radiographers or radiologists to improve

the visualization or to add markers and are sent again to be archived in the PACS, so that the processed image may be considered as a retake by the "online" system. A solution was to automatically detect these images by making use of the number of exposures on plate that is also archived in the DICOM header, which is the same number for original and reprocessed images. Additional information to the series and study descriptions is stored in the "image comment" field of the DICOM header. This field is particularly useful in the case of abdomen images because, in our case, it is used to indicate whether the image is taken with the patient in bipedestation or not.

The new set of criteria was applied to the 1,893 abdomen and 4,369 chest images archived in the PACS during a month, leading to a sample of 124 abdomen (6.6%) and 85 (1.9%) chest images that could be retaken images. The images finally considered as real repetitions by the radiologists were 62 abdomen (3.3%) and 38 (0.9%) chest images. Other causes of repetition like images taken in different days that are not really necessary, images repeated with a different identification, or repetitions due to a wrong orientation of the plate (landscape/portrait) in the first exposure are not detected by this automatic filtering of images.

0008 103E	Series Description	LO	16	tórax bucky PA
0008 1040	Institutional Department Name	LO	12	RADIOLOGIA
0008 1050	Performing Physician's Name	PN	18	DIAG.^POR^IMAGEN
0008 1090	Manufacturer's Model Name	LO	10	ADC_S1xx
0008 1120	Referenced Patient Sequence	SQ	1	
FFFE E000 (#1)	Item	(null)	UNDEFINED	(not loaded)
0008 0000	Group 0008 Length	UL	4	92
0008 1150	Referenced SOP Class UID	UI	24	1.2.840.10008.3.1.2.1.1
0008 1155	Referenced SOP Instance UID	UI	52	1.2.124.113532.10.35.45.126.20070118.125251.2895108
0010 0000	Group 0010 Length	UL	4	84
0010 0010	Patient's Name	PN	24	
0010 0020	Patient ID	LO	8	
0010 0030	Patient's Birth Date	DA	10	19410707
0010 0040	Patient's Sex	CS	2	M
0010 1010	Patient's Age	AS	6	065Y
0018 0000	Group 0018 Length	UL	4	204
0018 0015	Body Part Examined	CS	6	CHEST
0018 1000	Device Serial Number	LO	6	1020
0018 1004	Plate ID	LO	4	C63
0018 1020	Software Version(s)	LO	10	VIP51206
0018 1164	Imager Pixel Spacing	DS	30	1.14000000E-01\1.14000000E-01
0018 1260	Plate Type	SH	8	code15
0018 1401	Acquisition Device Processing Code	LO	14	600171a702Ra
0018 1402	Cassette Orientation	CS	10	LANDSCAPE
0018 1403	Cassette Size	CS	10	35CMx43CM
0018 1404	Exposures on Plate	US	2	1418
0018 5101	View Position	CS	4	PA

Fig 1. Example of a DICOM header with some of the fields used to automatically filter repeated images.

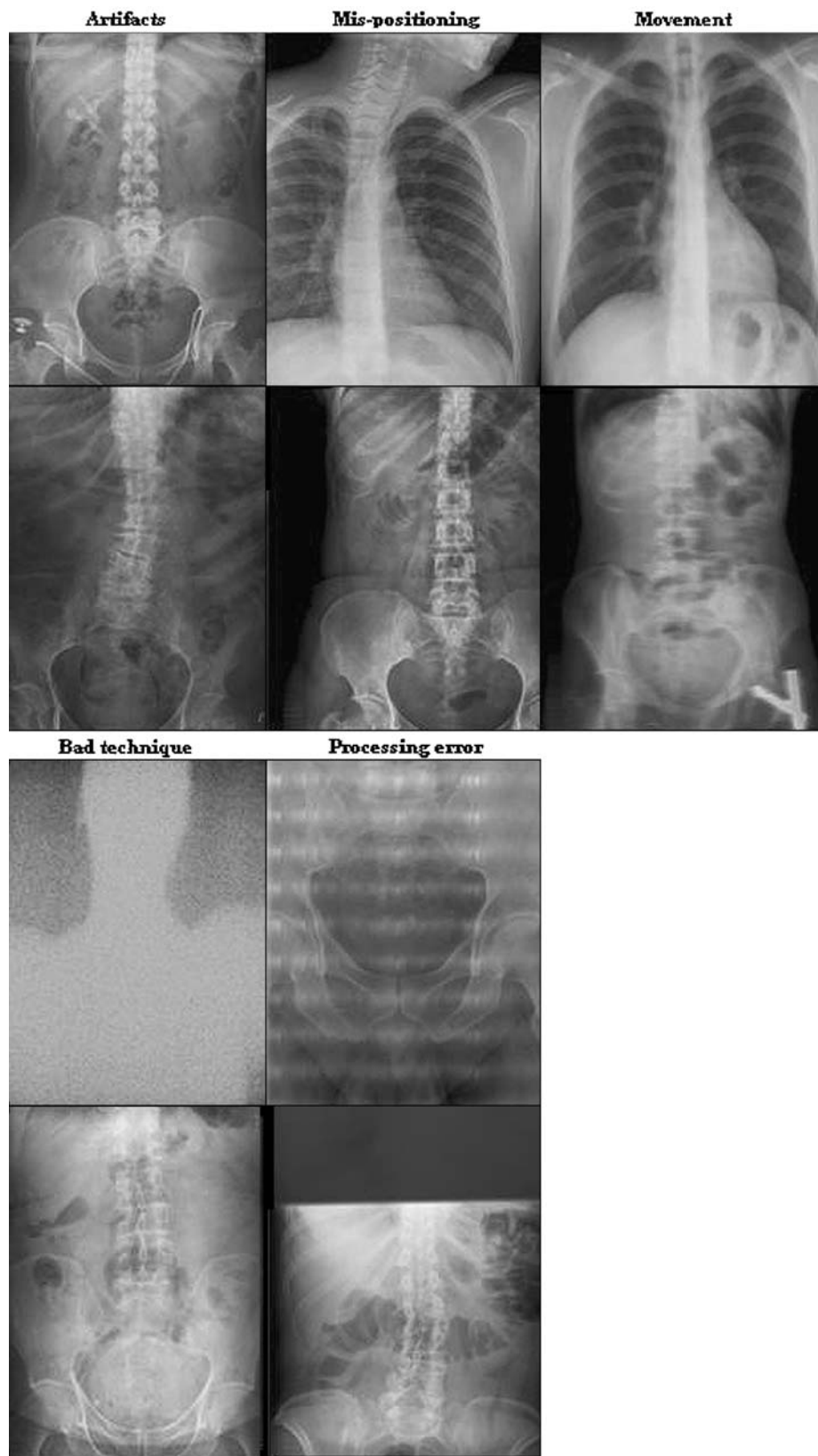


Fig 2. Examples of images retaken: artifacts (zip and hand on the abdomen), mispositioning, movement, bad technique (low technique), and processing error.

The causes of rejections were grouped in five categories:

1. Artifacts—jewelry, belt, or other radiopaque objects remaining in the way of the beam as well as scratch or dirt in the plate or in the cassette. In this group is also included double exposures of the same or different patients in a single plate.
2. Mispositioning—off-centered images, wrong collimation, or cassette mispositioned resulting in an image cut.
3. Movement—patient movement or motion of the area being imaged (incorrect breath holding).
4. Bad technique—inadequate inspiration or exposure (over/under). An inappropriate exposure may be caused by a selection of incorrect exposure parameters or by a wrong positioning of the patient in relation to the automatic exposure chambers. This fact that used to mean a film too dark or too pale in conventional radiography can be corrected in part by the wide dynamic range of the CR plates and with the post-processing. Nevertheless, in some cases, these corrections are not effective, especially if the radiographic technique that has been used is very far from the optimum. An acceptable range of values can be established for the parameter

“lgM” or the “logarithm of the median of the pixel value histogram” to detect this automatically, and therefore, we talk of high/low lgM images instead of too dark or too pale images.

5. Processing—corrupt images by malfunctions in the digitalization or archiving process (or during the network transmission).

Figure 2 shows some examples of images retaken.

About 50% of the chest image and 65% of the abdomen image retakes were due to mispositioning of the patient (see Fig. 3). Bad technique scored as second main cause of retakes. In some cases, more than one cause of rejection was found.

There were 50% of the abdomen and 45% of the chest images taken as repetitions by the automatic filtering that were not real retakes, as it was shown after the analysis image by image made by the radiologists. The automatic software selected them as repetitions because of:

1. Wrong identification. The image was not a repetition but a wrong identification (patient ID, study, or projection). This happened in (roughly) a 30% of the chest and an 80% of the abdomen images of this group (see Fig. 4).
2. Chest images taken in inspiration and exhalation.
3. Patient too large that could not be fully imaged with a plate. Therefore, two exposures were needed.
4. Plate not exposed or exposed without the patient.

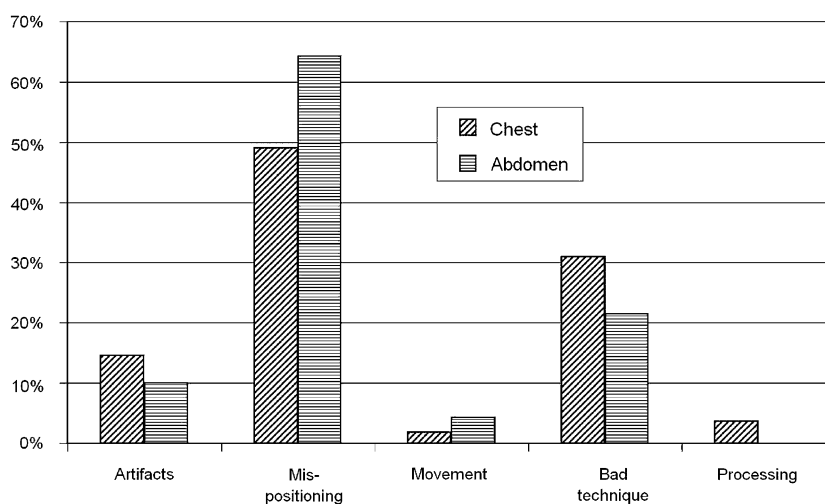


Fig 3. Reason for retaking a low-quality image. Causes of rejection of repeated images (3.3% of the abdomen and 0.9% of the chest images in the sample: 1,893 abdomen and 4,369 chest images archived in the PACS during a month).

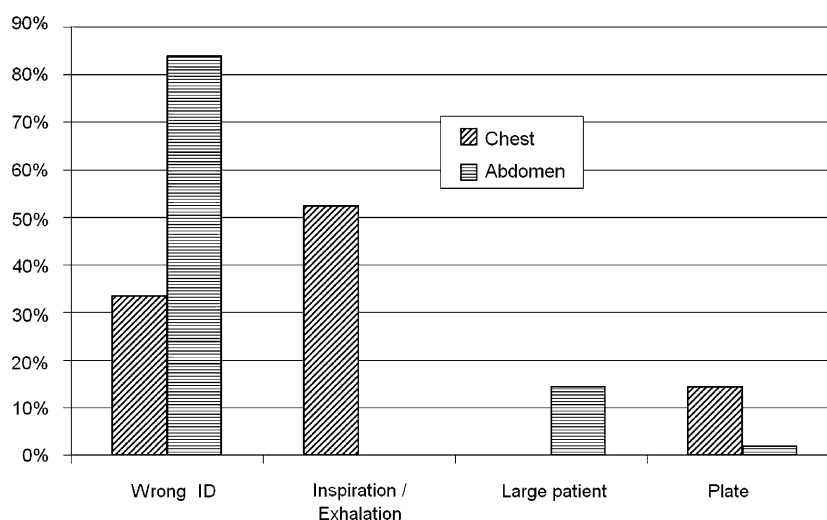


Fig 4. Reasons for the automatic filtering to wrongly identify a correct image as a retake (3.3% of the abdomen and 1.1% of the chest images in the sample: 1,893 abdomen and 4,369 chest images archived in the PACS during a month).

Corrective action taken to avoid these errors will be necessary in the future to improve the accuracy of the automatic retake analysis. Upcoming training programs for technologists in our hospital will emphasize the importance of an adequate identification and ways to avoid the most common mispositioning errors.

DISCUSSION

This work shows that a methodology to automatically detect potential retakes in digital imaging using DICOM header information is feasible. This pilot study can be easily extended to other modalities such as flat panel detector projection image. Besides, other approaches in the exploitation of data are possible using this methodology, such as variation on the number of retakes depending on the weekend, evening, or day shift. Rejection rate analysis could also be done if a tag is filled on every image rejected, but this implies a thorough collaboration of all radiologists and radiographers (not easy in very busy departments). The 'natural' tendency to mask poor-quality practice or the lack of consistency of all the staff to follow the procedure to mark or classify rejected images may easily lead to underreporting or misreporting of

rejected images. We have found a simpler, independent, and feasible way to face firstly the methodology to get automatically retake rates.

The incorporation of effective assessment strategies by which the level of service delivery can be measured is essential to evidence the quality of a service. Only where service levels are measured, analyzed, and remeasured after an intervention can we estimate the quality value of the intervention. One of this measurement tool is image retake analysis that facilitates a comparative measurement of aspects of service quality, providing evidence to direct staff training and education and alterations to work practice patterns that may be appropriate to improve service quality and facilitate cost-effective practice. Automatic algorithms can help in this task. The presented system allows to detect deficiencies like wrong identifications, positioning errors, wrong radiographic technique, bad image processing, equipment malfunctions, artifacts, etc. In addition, retake images automatically collected can be used for continuous training of the staff that, as shown in our case, should focus on the importance of an adequate identification and ways to avoid the most common mispositioning errors.

From our results, it seems that a right identification of images (specially in the abdomen where projections in lateral position are very often not

properly identified) and, in the case of chest images, a comment indicating whether the image was taken in inspiration or in exhalation could make the automatic filtering of information that appears in the DICOM header more useful for image retake analysis.

Other studies^{10,16,17} have described that most film-screen retakes were exposure and processing issues, while most digital retakes were due to a mispositioning of the patient, as it has happened in our case. The causes of repetition and the relative rates were similar in the abdomen and the chest images.

Based on the repetition rate, performance targets (such a certain reduction in the repetition rate or a reduction in the number of images wrongly taken as a repetition by the automatic software), can be set.

Appropriateness of exam has not been addressed yet, but the collaboration of radiologists putting tags to images that they judge as "not indicated" could be a first step to assess the justification of some radiographic exposures. Vendors could also help in future versions of the PACS by incorporating a user-friendly software to automatically store and classify rejected images.

CONCLUSIONS

The presented methodology to automatically detect potential retakes in digital imaging using DICOM header information is feasible and allows to detect deficiencies in the department performance like wrong identifications, positioning errors, wrong radiographic technique, bad image processing, equipment malfunctions, artifacts, etc. In addition, retake images automatically collected can be used for continuous training of the staff.

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REFERENCES

1. British Institute of Radiology: Quality Assurance in the Diagnostic X-ray Department, London: British Institute of Radiology, 1998
2. Dunn MA, Roger AT: X-ray film reject analysis as a quality indicator. *Radiography* 4:29–31, 1998
3. European Commission: Council Directive on Health Protection of Individuals Against Dangers of Ionising Radiation in Relation To Medial Exposures, and Replacing Directive 84/466/EURATOM, 97/43 Euratom, Brussels: European Commission, 1997
4. Boone JM, Cody DD, Fisher JR, et al: Quality Control in Diagnostic Radiology. Diagnostic X-ray Imaging Committee Task Group 12, AAPM report no. 74. American Association of Physicists in Medicine, Madison, WI: Medical Physics Publishing, 2002
5. Hardy M, Persaud A: The challenge of governance: achieving quality in diagnostic imaging. *Radiography* 7:159–163, 2001
6. Arvanitis TN, Parizel PM, Degryse HR, Schepper AMA: Reject analysis: a pilot programme for image quality management. *Eur J Radiol* 12(3):171–176, 1991
7. Gadeholt G, Geitung JT, Göthlin JH, Asp T: Continuing reject-repeat film analysis program. *Eur J Radiol* 9(3):137–141, 1989
8. Pitcher EM, Wells PN: Quality assurance and radiologic audit. *Curr Opin Radiol* 4(3):9–14, 1992
9. Freedman M, Steller D, Jafroudi H, Mun SK: Quality control of storage phosphor digital radiography systems. *J Digit Imaging* 8(2):67–74, 1995
10. Honea R, Blado ME, Ma Y: Is reject analysis necessary after converting to computed radiography? *J Digit Imaging* 15 (Suppl 1):41–52, 2002
11. Nol J, Isouard G, Mirecki J: Digital repeat analysis; setup and operation. *J Digit Imaging* 19(2):159–166, 2006
12. International Commission on Radiological Protection (ICRP publication 93): Managing patient dose in digital radiology. A report of the International Commission on Radiological Protection. *Ann ICRP* 34(1):1–73, 2004
13. Vano E, Fernandez JM, Ten JJ, et al: Dosimetry and image quality in digital radiology from online audit of the X-ray system. *Radiat Prot Dosim* 117(1–3):199–203, 2005
14. Faulkner K: The DIMOND project and its impact on radiation protection. *Radiat Prot Dosim* 117(1–3):3–6, 2005
15. SENTINEL: Safety and Efficacy for New Techniques and Imaging using New Equipment to Support European Legislation. European Coordination Action, (2005–2007). <http://www.sentinel.eu.com/Documents/Project+Presentation.pdf>. Accessed 7 April 2007
16. Peer S, Peer R, et al: Comparative reject analysis in conventional film-screen and digital storage phosphor radiography. *Eur Radiol* 9(8):1693–1696, 1999
17. Peer S, Peer R, et al: Comparative reject analysis in conventional film-screen and digital storage phosphor radiography. *Radiat Prot Dosim* 94(1–2):69–71, 2001

12.- Trabajo V

QUALITY CONTROL AND PATIENT DOSIMETRY IN DIGITAL RADIOLOGY. ON LINE SYSTEM: NEW FEATURES AND TRANSPORTABILITY

E. Vano^{1,2,*}, J. I. Ten³, J. M. Fernandez^{1,2}, C. Prieto¹, J. M. Ordiales¹ and D. Martinez¹

¹Medical Physics Department, San Carlos University Hospital, 28040 Madrid, Spain

²Radiology Department, Complutense University, 28040 Madrid, Spain

³Diagnostic Radiology Department, San Carlos University Hospital, 28040 Madrid, Spain

New features have been added to a system (QCONLINE) for auditing patient dosimetric and technical parameters 'on line', working on a digital radiology department and using the information contained in the DICOM header of some modalities. The audit of other parameters than patient doses have been included, setting alarm conditions to alert on malfunction of the X-ray system or bad operation modes, in addition to the evaluation of patient doses. A new module to analyse, collect and process the relevant information transferred by the modality performed procedure step (MPPS) service has been launched. Several examples with the exploitation of the new features are presented. The transportability of the system has been tested in two remote hospitals during several months. The new MPPS module has demonstrated to be a good tool to complement the information existing in the DICOM header. The system allows to help in the optimisation of digital radiology departments managing patient dosimetry and procedure data in real time.

INTRODUCTION

One of the deliverables during the European Coordination Action SENTINEL⁽¹⁾ has been the consensus on DICOM header management to improve the aspects of radiation protection and quality management in interventional radiology (IR).

The DICOM header of archived images (or fluoroscopy runs) contains very useful information for patient dosimetry and quality control during fluoroscopically guided procedures (also for other radiology procedures). It should be considered a priority in the future to enrich and standardise this information by the radiology industry and to do it such as to make it easily available to the users. The capability to transfer this information to a database for further utilisation should also be part of the goal.

The International Commission on Radiological Protection published a document on patient dose management on digital radiology⁽²⁾ highlighting that digital radiology (DR) represented one of the greatest technological advances in medical imaging over the last decade. It has the potential to reduce patient doses, but also the risk to increase the number of exposures and the dose required to obtain images of enough quality. Experience has shown that although many radiology departments have made the transition to digital equipment, patient doses have not gone down but have measurably increased⁽³⁾. ICRP states that real-time collection of dose data, would facilitate management of dose and help to prevent excessive patient doses. The desired situation in the

future for different digital technologies would be the automatic extraction of the information from the DICOM header and archive in the radiological information system (RIS) or picture archiving and communication system (PACS).

In a previous paper⁽⁴⁾, an auditing on line system was described based in the processing of the information from the DICOM header. That system was not restricted to only patient doses; data on relevant exposure parameters and details on the imaging procedure and a link with images were also provided. Demographic and technical data were implemented allowing image quality to also be audited and to accomplish the whole quality control (QC) process on an individual basis, if required, keeping dosimetric and procedural parameters related with the clinical images.

In the present paper, new features added to the system are described. It is possible to set alarm conditions alerting on malfunction of the X-ray system or bad operation modes, in addition to the values of patient doses. A new module to analyse, collect and process the relevant information transferred by the modality performed procedure step (MPPS) DICOM service has been launched and the transportability of the system to other centres has been tested. These results will complement the work in progress of a joint group between IEC and DICOM⁽⁶⁾.

MATERIAL AND METHODS

QCONLINE has been developed in Microsoft Visual Basic 6.0 with a database under Microsoft SQL Server 2005 as previously described⁽⁴⁾.

*Corresponding author: eliseov@med.ucm.es

The new features developed, allow to use trigger (alarm) levels for mean values (derived from a group of procedures, typically for the last 30) or for individual patients. Each parameter audited in every incoming image can be filtered by modality, station name (X-ray system or computed radiography (CR) digitiser), study description and view position. Upper, lower, equal or not equal algorithms can be active on demand.

These individual alarm conditions can trigger investigation on the causes of high doses or take decisions on patient clinical follow-up for skin injuries, after IR procedures. Technical parameters (kV, mAs, radiation field size, etc) and details of operational practice (compression strength in mammography, proper automatic exposure control sensor choice, etc) are audited, using data available in the DICOM header. For CR, the exposure dose index and post processing parameters are audited. For IR, the number of images per series, the total number of series and the total number of images per procedure are also susceptible of generating alarms. When some X-ray systems include in the DICOM header the air kerma area product (KAP) and the cumulative air kerma incident dose at the interventional reference point (IRP) for the different series of images (e.g. Siemens Axiom Artis), these values can also be used to trigger alarms.

The QCONLINE system has been 'packed' to be distributed to some Radiology Departments interested to participate in a trial exercise in the Autonomous Community of Madrid (Spain), to be later extended to other European Centres. This pack includes the Microsoft SQL Server Database (DICOM.mdf) with the DICOM and trigger configuration, and the 'setup' file to install the graphic user interface to display DICOM images, trigger configuration and trends of some parameters in a Microsoft Windows System environment.

With the same methodology as QCONLINE, an MPPS Service Class Provider has been launched to receive information on the acquisition parameters, patient dose, and other data related to the whole examination as what study has been really performed by the modality. This DICOM Service is installed like a true Microsoft Windows Service, and when it is running, the system 'listen' by one standard DICOM Port (identified as: 3320) in order to archive the MPPS messages sent by the modality when the study is completed.

RESULTS

The QCONLINE system has been shown to be useful to obtain information on real time from the audited parameters and generate corresponding alarms. Figure 1 shows an example of the alarm generated by a low compression strength in mammography. In the

lower part of the screen, the graph shows that two images have been obtained without compression, whereas in the upper part of the screen, the correction action result is presented: the two following images with the appropriate compression.

The tool allows setting individual trigger levels for the incoming images. For CR modality, the trigger permits the detection of images acquired by the different stations (digitisers) having an exposure level (AGFA private attribute 0019,1015) out of the range established by the user.

The QCONLINE system has been 'transported' and tested in two remote Centres. In the first trial, it was connected directly to an IR modality (Siemens Axiom Artis). The trial took about 6 months and 100 studies were received and audited. The DICOM header contents of this modality was useful to analyse parameters such as KAP per series, cumulative air kerma at the IRP per series, C-arm angulations, focus-table distances, number of frames/series, series/study, etc. In the second centre, the QNONLINE was connected to a PACS of the radiology department but two important difficulties were found:

- The contents of the DICOM headers were very poor, in many cases only date, time and unique identifiers (UID) elements were available, making impossible any useful audit.
- The PACS only offered the possibility to route the images very compressed (40:1 compression ratio) and the evaluation of image quality was not affordable.

The development of the MPPS module has permitted one to analyse the information contained in every MPPS message, and to identify for each modality which information is useful. It has been necessary to develop this module because neither PACS nor RIS installed in our centre provided support for MPPS



Figure 1. Example of the alarm generated by a low compression strength in mammography.

Table 1. Information extracted from XA MPPS message.

(0008,0060): 1: Modality: XA
 (0008,1032): 0: Procedure Code Sequence:
 (0008,1120): 0: Referenced Patient Sequence:
 (0010,0010): 1: Patient's Name: xxxx
 (0010,0020): 1: Patient ID: 1492803
 (0010,0030): 0: Patient's Birth Date:
 (0010,0040): 0: Patient's Sex:
 (0018,115E): 0: Image Area Dose Product:
 (0020,0010): 1: Study ID: NEFROSTOMIA
 (0040,0241): 1: Performed Station AE Title: IBIS3_RIS
 (0040,0242): 1: Performed Station Name: 52314
 (0040,0243): 0: Performed Location:
 (0040,0244): 1: Performed Procedure Step Start: 24/12/2006
 (0040,0245): 1: Performed Procedure Step Start: 11:00:21
 (0040,0250): 1: Performed Procedure Step End D: 24/12/2006
 (0040,0251): 1: Performed Procedure Step End T: 12:05:20
 (0040,0252): 1: Performed Procedure Step Status: COMPLETED (0040,0253): 1: Performed Procedure Step ID: E200612241100187
 (0040,0254): 0: Performed Procedure Step Description:
 (0040,0255): 0: Performed Procedure Type Description:
 (0040,0260): 0: Performed Action Item Sequence:
 (0040,0270): 1: Scheduled Step Attributes Sequence:
 Sequence of 1 items:
 (0008,0050): 1: Accession Number: xxx
 (0008,1110): 0: Referenced Study Sequence:
 (0020,000D): 1: Study Instance UID:
 1.3.46.670589.28.3711508483448.20061224100021042.84515
 (0032,1060): 0: Requested Procedure Description:
 (0040,0007): 0: Scheduled Procedure Step Description:
 (0040,0008): 0: Scheduled Action Item Code Sequence:
 (0040,0009): 0: Scheduled Procedure Step ID:
 (0040,1001): 0: Requested Procedure ID
 (0040,0300): 1: Total Time of Fluoroscopy: 397
 (0040,0301): 1: Total Number of Exposures: 0
 (0040,0302): 1: Entrance Dose: 2
 (0040,8302): 1: Entrance Dose in mGy: 183.36777
 (0008,103E): 1: Series Description: Fluoroscopy
 (0008,1050): 0: Performing Physician's Name:
 (0008,1070): 0: Operators' Name:
 (0008,1140): 1: Referenced Image Sequence: Sequence of 1 items:
 (0018,1030): 1: Protocol Name: Abdomen 2D

service. In the future, an automatic extraction of the information will be necessary to archive only selected messages for each study. Table 1 shows the most relevant information extracted from the MPPS messages sent by an X-ray angiographic image (XA) modality. It is noticeable that some information received is not available in the DICOM header of the images (e.g. total KAP, fluoroscopy time, etc) and MPPS is, at present, the only way to keep these data.

DISCUSSION AND CONCLUSION

The new features of the QCONLINE allow auditing any parameter included in the DICOM header,

setting alarms for mean values in a group of images or in individual images.

For CR, the most useful parameter to audit has been the exposure dose index and the post processing parameters. For IR, the number of images per series, the total number of series and the total number of images per procedure (and in some systems, the KAP and cumulative air kerma at the IRP). The information about C-arm angulations will allow setting alarms when a high concentration of radiation fields occurs in a region of the patient's skin during interventional procedures.

This QCONLINE, developed under the DIMOND and SENTINEL European research projects⁽¹⁾ has demonstrated the benefits of some ICRP recommendations for DR⁽²⁾.

Until the radiology industry implements the new IEC-DICOM dose standard⁽⁶⁾, the MPPS service is a useful complementary tool to audit dose parameters for complex procedures as IR and CT.

The transportability of the QCONLINE system has been tested and more centres will have the opportunity to take benefit of this development in the future.

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REFERENCES

1. SENTINEL. Safety and Efficacy for New Techniques and Imaging using New Equipment to Support European Legislation. European Coordination Action (2005–2007). <http://www.sentinel.eu.com/Documents/Project+Presentation.pdf> (Accessed 7 April 2007).
2. International Commission on Radiological Protection. *Managing patient dose in digital radiology*. ICRP Publication 93. Ann ICRP. **34**(1), 1–73 (2004).
3. Vano, E., Fernandez, J. M., Ten, J. I., Prieto, C., Gonzalez, L., Rodriguez, R. and de Las Heras, H. *Transition from screen-film to digital radiography: evolution of patient radiation doses at projection radiography*. Radiol. **243**(2), 461–466 (2007).
4. Vano, E., Fernandez, J. M., Ten, J.I., Gonzalez, L., Guibelalde, E. and Prieto, C. *Patient dosimetry and image quality in digital radiology from online audit of the X-ray system*. Radiat. Prot. Dosim. **117**(1–3), 199–203 (2005).
5. European Commission. Council Directive 97/43 Euratom on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466 Euratom. Off. J. Eur. Commun. **L180**, 22–27 (1997).
6. IEC. *New work item proposal. medical electrical equipment. radiation dose documentation. part 1: Equipment for radiography and radioscopy*. 62B/645/NP, Date of circulation 2007-01-19.

13.- Trabajo VI

Skin dose and dose–area product values for interventional cardiology procedures

^{1,2}E VANO, PhD, ²L GONZALEZ, PhD, ³J I TEN, BSc, ^{1,2}J M FERNANDEZ, BSc,
²E GUIBELALDE, PhD and ³C MACAYA, PhD

¹*Medical Physics Service and* ³*Cardiology Service, San Carlos University Hospital and* ²*Radiology Department, Medicine School, Complutense University, 28040 Madrid, Spain*

Abstract. Coronary angiography and percutaneous transluminal coronary angioplasty procedures performed in four different facilities were monitored in the present study by measuring maximum skin dose, dose–area product and other operational parameters. Radiographic slow film, thermoluminescent dosimeters and transmission ion chambers were used to measure dose related quantities. Values of 107–711 mGy for maximum skin dose and 27.3–370.6 Gy cm² for dose–area product were found, together with cumulative skin dose estimates of 110–3706 mGy. A discussion of the relationship of measured dose–area product and skin dose values is made using a field concentration factor defined as a way to interpret the findings. No general correlation was observed between dose–area product and maximum skin dose. Cumulative skin dose estimates throughout a procedure should be discarded as a realistic method for assessing deterministic risk in cardiology procedures. Slow film in addition to thermoluminescent dosimeters for measurement of maximum skin dose is a good alternative, especially for complex interventional procedures. For repeated procedures, combining film and dose–area product monitoring favours optimization of radiation protection for the patient.

Some X-ray cardiology procedures can produce skin injuries to the patients, among other hazards [1–11]; there are also associated relatively high risks for staff [11–13]. Dose–area product (DAP) is a good quantity for estimating stochastic risk for the patient [14, 15]. Transmission ionization chambers are being installed in some modern X-ray systems for interventional procedures. In addition, DAP values have been recorded in some centres, and local dose reference values for patients have been proposed in recent years [11, 16–19], as recommended by the International Commission on Radiological Protection (ICRP) [20]. Monte Carlo factors for calculating organ and effective doses in cardiology procedures have also been published [14].

As an optimization action to reduce the risk of deterministic effects in patients undergoing long cardiology procedures or procedures with non-optimized X-ray equipment, maximum skin dose (MSD) should also be evaluated. Correctly positioned thermoluminescence dosimetry chips could provide these data, but the location of the most heavily irradiated areas cannot be predicted and large chip numbers would be required,

thereby making their routine use impractical. A feasible solution is to use slow X-ray film as a detector [21–23]. Film location is much less critical than for thermoluminescent dosimeters (TLDs), and dose estimation can improve reliability since the different irradiated areas are visualized directly on the film. In addition, it is possible to evaluate the use of collimation, edge filters, etc., which will permit retrospective optimization of the procedure protocol.

Concern about skin injuries in X-ray cardiology procedures is widespread. The Food and Drug Administration (FDA), the World Health Organisation, the ICRP and the International Atomic Energy Agency have published (or are producing) documents [24, 25] to avoid deterministic effects in cardiology procedures. At the same time, different working methods, instrument arrays and designs to improve radiation protection and measurement capabilities are being developed and evaluated [26–35]. Moreover, training of physicians in radiation protection and radiation management as a means of reducing doses in each specific procedure is encouraged [20, 36–38].

The International Electrotechnical Commission is also preparing a set of standards entitled “Particular requirements for the safety of x-ray equipment for interventional procedures”; the document examines dosimetric measurements, and both DAP and skin dose are regarded as

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Address correspondence to Professor E Vano, Catedra de Fisica Medica, Facultad de Medicina, Universidad Complutense, 28040 Madrid, Spain.

possible estimators [39]. However, it is also well known that skin dose is not easy to measure, particularly in cardiology procedures where the X-ray beam enters the patient by several sites and the field size varies widely. Estimations based on the output rate of the X-ray tube, using tube potential (kV) and tube current (mA) settings, usually give unrealistic results in cardiology procedures, since the irradiated area and the focus-to-skin distance are often changed. Therefore, research and development of suitable monitoring systems are required [40].

This paper presents experimental DAP and MSD data from coronary angiography and percutaneous transluminal coronary angioplasty (PTCA) procedures from four cardiology facilities in three hospitals. The data substantiate the influence of both the protocol applied by the cardiologist carrying out the procedure and the pathology of the patient in DAP and MSD values measured. In view of the variability in such data, another purpose of this report is to alert medical specialists to the importance of adopting simple, conservative attitudes with respect to radiation protect. In addition, we wish to warn medical physicists that DAP, or other approximations based on X-ray tube output rate, are not sufficient to estimate MSD in cardiology procedures.

Methods

Coronary angiography and PTCA procedures were monitored in three hospitals, with three different teams of cardiologists, on a non-selected subset of patients for whom relevant data were recorded. One of the centres has two laboratories dedicated to cardiology procedures. One laboratory has a Philips Integris HM3000 (Philips Medical Systems, The Netherlands), configured specifically for cardiology with a built-in "spectra beam" system (high filtration in the X-ray beam), identified in this paper as HC-I. The second laboratory has a Philips Optimus M-200 system, identified as HC-O. The other two centres, identified as RI and RJB, are both equipped with ADVANTX systems (GE Medical Systems, Milwaukee, WI) configured for cardiology and vascular studies. Only the Integris system is equipped with a DAP meter. Output constancy in the X-ray systems was checked periodically, with satisfactory results.

Slow film dosimetry was selected as the method for dose monitoring, using Kodak X-Omat V films (Eastman Kodak Co., Rochester, NY), commonly available in hospitals having radiotherapy facilities. Previous sensitometry tests and calibration for dose measurements were carried out for typical beam qualities used in cardiology

procedures [23]. Films were processed in a Kodak X-Omat-M6B system (with Kodak chemicals). Optical density was measured using a digital Victoreen 07-424 densitometer (Nuclear Associates Victoreen, Cleveland, OH). The highest readable dose at the linear part of the sensitometric curve was about 700 mGy, a value greater than the doses usually measured in most procedures. Precision of values on the sensitometric curve shoulder was rather poor.

Between four and eight lithium fluoride TLD-100 chips, individually calibrated to the X-ray diagnostic energies, from Harshaw TLD/Bicron/NE-Technology (BICRON-NE, Solon, OH), were also used to measure dose by placing them in contact with the films at locations where the highest irradiation would be expected (based upon results from previous similar procedures and the view of the individual conducting the intervention). Data from both the film and the TLD readings were used together, the latter providing readings from the most irradiated area to reduce dose uncertainties in estimating MSD. Some results from TLDs were rejected on account of improper chip placement if no chip was located in the highest optical density film area.

The TLD reader was a System Model 4400 from Harshaw (Harshaw Filtrol Partnership, Solon, OH). DAP measurements were made with Diamontor transmission ion chambers (PTW-Freiburg, Germany).

Reliability of the transmission ion chambers and the TLD system was checked periodically by comparing their readings with those from a Victoreen calibrated ion chamber (model Rad-Check) and deriving correction factors. Measurement reliability was confirmed to be within 12% for the transmission chambers, with an overall uncertainty (in measurement accuracy) not greater than 15%. Uncertainty of TLD readings was below 7% for the overall dose range throughout the work. Dose estimate errors due to changes in film speed and contrast in the range of X-ray tube potentials used were less than 10%. MSD determined by film and TLDs were fully compatible, with discrepancies below 15%. Uncertainties quoted include detector response changes with the different X-ray beam qualities used.

To assess the radiation field concentration during a cardiology procedure, a concentration factor has been assessed, calculating the ratio between (i) the MSD and (ii) the average dose obtained as the quotient of DAP and the total irradiated area. If a cardiology procedure is performed with radiation fields often located in given skin regions, its concentration factor will exhibit a higher value than for another procedure carried out using more distributed fields; thus,

the concentration factor may help to compare cardiology procedures of similar complexity, performed with a given clinical protocol.

An estimate was made for the typical time and the number of images in lateral projections (not imaged by the film under the patient), based on previous survey and the opinion of the individual conducting the procedure, as well as the total irradiated area. Mean field size was calculated from the darkened areas on the slow film, and the quotient between DAP and the mean field size gave the total incident air kerma at skin level.

Results

Table 1 presents the results obtained from 26 coronary angiography and 7 PTCA procedures, from which a comprehensive follow-up with DAP records, TLD measurements and slow film images was completed. There is major uncertainty where doses are shown as >700 mGy, as they were estimated only by film density on the shoulder of the sensitometric curve and were not measured by TLDs because of the unsuitable location of the TLD chips. Experimental values were:

Table 1. Dosimetric parameters for monitored procedures

Procedure No./Centre	Mean field size (cm ²)	DAP (Gy cm ²)	Fluoroscopy time (min)	No. of images	MSD (mGy)	Total irradiated area (cm ²) ^a	Concentration factor	Total incident air kerma at skin level (mGy)	Average dose (DAP/total irradiated area)
CG 19/RJB	215	96.7	4.4	981	107	850	1 ^b	449	114
CG 44/RJB	130	63.3	3.1	622	270	500	2.1	487	127
CG 49/RJB	170	84.4	8.2	932	115	830	1.1	496	102
CG 50/RJB	160	143.3	7.2	1332	678	850	4	896	169
CG 52/RJB	230	145.6	4.3	893	160	850	1 ^b	633	171
CG 53/RJB	220	132.9	8.3	1023	223	1300	2.2	604	102
CG 36/RI	120	230.0	23.4	na	711	663	2	1920	347
CG 37/RI	90	75.9	4.6	na	159	788	1.7	843	96
CG 38/RI	90	136.4	4.3	na	314	671	1.6	1515	203
CG 23/HC-I	140	75.2	7.3	na	180	700	1.7	537	107
CG 47/HC-I	90	27.3	4.2	836	128	600	2.8	303	46
CG 58/HC-I	110	32.6	2.3	459	49	450	1 ^b	296	72
CG 69/HC-I	90	27.8	3.3	665	110	1100	4.4	310	25
CG 24/HC-O	88	29.7	2.4	639	132	413	1.8	340	72
CG 25/HC-O	75	82.3	11.7	720	190	426	1 ^b	1097	193
CG 27/HC-O	71	40.3	5.5	585	296	836	6.2	570	48
CG 29/HC-O	53	35.2	2.2	630	153	567	2.4	664	62
CG 33/HC-O	120	104.2	7.6	1305	362	725	2.5	869	144
CG 34/HC-O	60	98.5	12.2	1125	161	780	1.3	1642	126
CG 56/HC-O	90	48.0	3.3	667	130	800	2.2	533	60
CG 57/HC-O	90	44.1	7.6	988	161	900	3.3	490	49
CG 61/HC-O	120	70.3	4.8	922	193	800	2.2	586	88
CG 63/HC-O	90	37.3	na	na	175	800	3.7	414	47
CG 67/HC-O	110	39.6	na	na	100	860	2.2	359	46
CG 68/HC-O	130	78.9	9.3	1393	310	1400	5.5	607	56
CG 71/HC-O	120	74.3	4.4	766	226	800	2.4	619	93
PTCA 21/HC-O	120	69.3	16.3	435	187	450	1.2	578	154
PTCA 28/HC-O	88	52.7	9.5	540	>700	704	>9	599	75
PTCA 30/HC-O	100	33.7	5.3	540	507	705	10.6	337 ^c	48
PTCA 31/HC-O	72	102.9	19.6	900	457	630	2.8	1429	163
PTCA 32/HC-O	68	89.6	15.4	1215	169	680	1.3	1318	132
PTCA 35/HC-O	72	73.7	12.2	855	>700	518	>5	1023	142
PTCA 48/HC-O	100	370.6	59.2	627	274	1100	1 ^c	3706	337

DAP, dose-area product; MSD, maximum skin dose; CG, coronary angiography; PTCA, percutaneous transluminal coronary angioplasty.

^aIncludes an estimate of the lateral projections imaged.

^bConcentration factors are slightly below 1, but in good agreement with experimental uncertainties.

^cLateral projection areas are probably not well estimated, which would affect the actual value of mean field size. In PTCA 30, values of MSD and total incident air kerma at the patient skin level could be compatible, keeping in mind experimental uncertainties. PTCA 48 yielded an abnormal concentration factor of 0.8.

MSD, 107–711 mGy (including backscatter); fluoroscopy time, 2.2–59.2 min; cine frames, 435–1393; mean radiation field size at the entrance of the patient, 53–230 cm²; total irradiated skin area, 245–1400 cm²; and DAP, 27.3–370.6 Gy cm². Values for concentration factor, calculated as described in the previous section, are also presented.

Results presented here depict a rather small set of data to perform any statistical analysis, and thus statistical analysis is deliberately omitted.

Constancy checks at the RJB centre (under a special survey because of its comparatively high DAP values) yielded dose rates at the entrance of the image intensifier from 0.5–2.1 µGy s⁻¹, from low to high fluoroscopy modes, for a field size of 22 cm diameter and measured with a grid. This can be considered fairly normal. This is also true for values of dose per frame (0.2–0.6 µGy frame⁻¹ for the four cine modes, allowing four levels of image quality).

Discussion

All experimental values measured lay in a wide range, suggesting different levels of difficulty in the procedures and that optimization from the patient radiation protection approach was not entirely achieved. Nevertheless, the eventual aim of creating a statistically significant database to derive difficulty levels and related parameters will require a great deal of effort in establishing a realistic variation range and subsequent reference values.

In general, DAP values are comparatively high at the RJB centre (mean 111.02 Gy cm²) owing to the higher mean field size (188 cm²), while the average fluoroscopy time (5.1 min) and number of images (964) were comparable with local reference values [18].

For coronary angiography procedures, staff of the HC-O facility seem to be more conservative regarding radiation protection, giving a mean field size of 94 cm². Other mean values from the 13 procedures monitored in this system are 60.2 Gy cm² DAP, 6.5 min for fluoroscopy time and 885 for mean number of frames. Figure 1 shows images of irradiated areas for coronary angiographies No. 27 and No. 57 performed with this system. Figure 2 presents images from procedures No. 37 and No. 53 to appraise the differences in beam collimation.

Excluding isolated cases, DAP and skin dose values are independent quantities in practice, even for a given X-ray system or a specific procedure and protocol. For example, coronary angiographies No. 33 and No. 34 show similar DAP values (and were carried out by the same staff

and X-ray system), but skin doses do not show a similar correlation owing to the uneven concentration of radiation fields on the patient's skin. Comparison of MSD and DAP with reference values, once they have been established, would provide a suitable method to optimize the protocol.

Cardiology procedures with large concentration factors, if repeated, would have a higher risk of deterministic effects than other procedures with a lower concentration factor. Thus, this factor can be used together with MSD and DAP as a complementary risk indicator, particularly in procedural repeats or for audits. It establishes a link between MSD and DAP, which requires a rather cumbersome analysis of results, but there is no other easy way to establish such a relationship.

An equal concentration factor in two different procedures with similar total irradiated area would yield proportional values of DAP and MSD, as in coronary angiographies No. 37 and No. 38, for example. This particular result helps explain the general lack of correlation between both radiological quantities.

The definition of concentration factor means that if the average doses used in its calculation (last column in Table 1) are similar for all procedures, the relationship between concentration factor and deterministic risk becomes closely correlated; that is, MSD becomes almost proportional to concentration factor in each procedure. Thus, the concentration factor may also help to classify the interventions according to their complexity. To what extent similar average dose is usual in interventional procedures is the obvious point to study prospectively, and this reinforces the need for further experimental work in this field. However, one can see in the data from the RJB centre how the situation is approximately fulfilled, albeit that the statistical significance is poor to assess the circumstances where similarity could be expected.

The above considerations may be important in the case of PTCA, as shown in Table 2 for 4718 PTCA clinical histories from the HC centre. As can be seen from these data, more than 18% of patients undergo two or more procedures. Of these, more than 5% undergo three or more procedures.

In some cases, patient pathology and clinical protocol could, by themselves, explain the lack of correlation between DAP and MSD. For example, in Table 1, data on DAP, fluoroscopy time and number of frames suggest a lower risk for coronary angiography No. 27 than for No. 57, but the higher field concentration of No. 27 (6.2 vs 3.3) causes a nearly two-fold MSD. In cases No. 31 (PTCA alone) and No. 32 (PTCA + coronary angiography), the different protocols

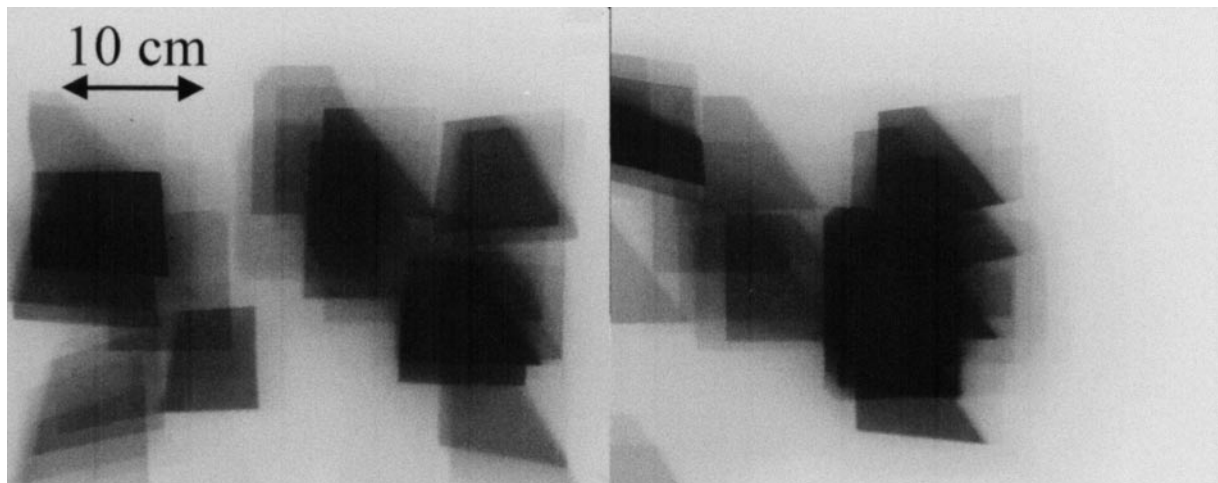


Figure 1. X-ray field images from coronary angiography procedures performed in facility HC-O. Procedure No. 27 (right) yielded a dose-area product (DAP) of 40.3 Gy cm² and a maximum skin dose (MSD) of 296 mGy, with a mean field size of 71 cm² and a total irradiated area of 836 cm². Data from procedure No. 57 (left) were 44.1 Gy cm² DAP and 161 mGy MSD with a mean field size 90 cm² and a total irradiated area of 900 cm². Note that DAP and mean field size were higher in No. 57 for a similar irradiated area, but that MSD was higher in No. 27 owing to higher field concentration. Accordingly, the concentration factor is 6.2 for No. 27 and only 3.3 for No. 57.

give rise to different MSDs of 457 mGy and 169 mGy, respectively.

Coronary angiography No. 34 would be an example of good radiation protection practice. In spite of a longer fluoroscopy time than usual and a significant frame number, DAP and MSD values are low. Collimation, use of an edge filter and absence of significant field overlapping have resulted in low dose values and a low concentration factor. This is further indicated by the discrepancy between MSD and total incident air kerma at the patient skin level (see Table 1). The last quantity would roughly match the data supplied by an online patient exposure meter [13] under the assumption that the X-ray beam had

constant incidence throughout the procedure, once corrected for backscatter, mass energy absorption coefficient and table attenuation, if necessary. Note that differences of more than one order of magnitude in the value of MSD for the same incident air kerma have been found. Thus, the total incident air kerma cannot predict risk in all situations, contrary to the assertion of some equipment manufacturers [32] who install such a meter in the X-ray system to determine a “cumulative procedural radiation dose” (Patient Exposure Management NETWORK—PEMNET—System from Clinical Microsystems, Inc., Arlington, VA) to assess deterministic risk. Cusma et al [41] have used a PEMNET system

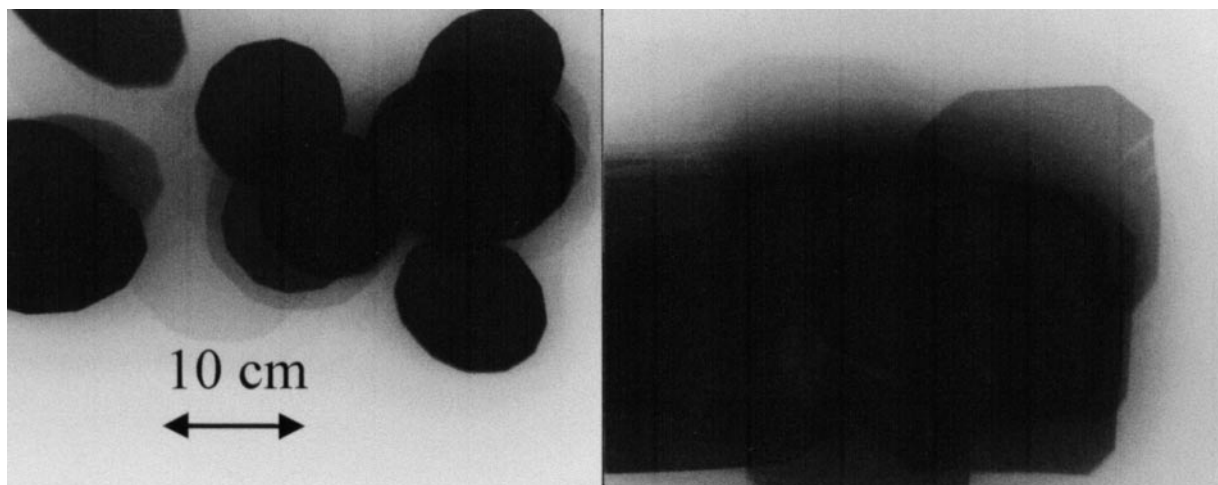


Figure 2. X-ray field images from coronary angiography procedure No. 37 performed in facility RI (left) and procedure No. 53 performed in facility RJB (right), illustrating differences in beam collimation between them (larger fields and quite superimposed in No. 53 compared with No. 37) and with respect to Figure 1.

Table 2. Repetition rate of percutaneous transluminal coronary angioplasty hospital procedures (3777 patients; 4718 procedures over 38 months)

Procedures per patient	1	2	3	4	5	6	7	8&9
No. of patients	3099	485	148	33 ^a	6 ^b	2 ^c	2	2 ^d

^a One patient underwent four procedures in less than 1 month.

^b One patient underwent five procedures in 9 months.

^c One patient underwent six procedures in 15 months.

^d One patient underwent nine procedures in 38 months.

to perform real-time radiation exposure monitoring during different interventional procedures, stating that their totals do not represent the total exposure to any single area of skin. Therefore, a real-time display of the cumulative exposure incurred throughout a procedure can lead to a conservative attitude in respect to radiation protection, as a DAP meter could do, but it can hardly be used to perform a follow-up of the exposure in a given skin region. Regarding this point, the European Directive 97/43/Euratom [42] makes compulsory in new radiodiagnostic equipment, where practicable, a device informing the practitioner of the quantity of radiation produced by the equipment during the radiological procedure. Spanish Decree 1976/1999 [43] includes this point of the Directive and reinforces its contents by requiring that equipment used in interventional procedures (in service as well as new facilities) shall include a radiation measurement + recording device. However, none of these measures will guarantee patient doses under deterministic levels, and values measured in a given procedure, even in a sample of a given type of intervention, should be carefully used to establish diagnostic reference levels for such a practice alluded to in Directive 97/43 for the adoption of conservative values. This problem is emphasized in the Radiation Protection 109 document of the European Commission [44].

High concentration factors help to illustrate how difficult it is to predict MSD. In PTCA No. 28 and No. 30, for example, MSDs are high and irradiated areas are relatively large ($>700 \text{ cm}^2$), with low DAPs. In either case, the field overlap and the concentration of fluoroscopy in a specific skin region (mainly anteroposterior projection was used) could explain the situation.

Two remarks can be made about the data presented here. First, differences of only 5% in DAP could be associated with skin doses varying by as much as a factor of 2, as in coronary angiographies No. 33 and No. 34. Second, relatively low values of DAP could be associated with high skin doses, as in PTCA No. 30. Therefore, in

most cases it is not possible to predict MSD using only DAP values. A complementary procedure for skin dose measurements is necessary. From the available data, monitoring based on TLD matrix arrays such as described by Braunlich [28] and evaluated by Geise et al [29, 30] seems adequate but rather burdensome and expensive on a routine basis. Furthermore, use of slow film also seems a valid alternative, although high doses and risky skin locations become time-delayed information. However, an indication derived from total incident air kerma or exposure at the skin level of the patient [31] is not always a practical option when the incidence of the X-ray beam is variable, as in the case of cardiology procedures.

From the above comments, one could infer that the cardiologist's skill and the will to reduce risks in the procedure would play a major role quite apart from the influence of the X-ray system [35, 45]. Thus, assuming that a certain fluoroscopy time and a certain number of images are justified for the medical result, a pragmatic approach to reducing skin dosage would be to adopt a conservative attitude towards radiation protection in all circumstances. To this end, considerations regarding dose rate outputs for a given system lose a major part of their relevance, provided the system exhibits normal performances, and one should follow instead some simple points already stated in the FDA Public Health Advisory Bulletin of September 1994 [24]. Such points should only take into account the chief factors influencing MSD, such as X-ray equipment performance capabilities, patient size and patient pathology. These factors can be summarized as:

- keep image quality level at the minimum required for the medical output;
- use magnification only when necessary;
- change beam direction whenever possible; and
- use beam collimation and edge filters to avoid field overlap.

With the aim of predicting and avoiding patient deterministic effects, patient pathology is critically important, especially in the light of data presented in Table 2. The concentration factor, or an estimate based on the discrepancy between MSD and total incident air kerma at the patient's skin, when available, may be helpful in the adoption of radiation protection measures on an individual patient basis. Therefore, we believe it is advisable to introduce a technique of combined film and DAP monitoring, at least for patients that will undergo several cardiology procedures, to estimate the total incident skin dose in repeated procedures and thereby optimize radiation protection, especially if the threshold of deterministic effects might be exceeded.

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References

- Wagner LK. Typical doses and biological implications. In: RSNA categorical course in diagnostic radiology physics: cardiac catheterization imaging. RSNA, 1998:249–54.
- Wagner LK, MacNeese MD, Marx MV, Siegel EL. Severe skin reactions from interventional fluoroscopy: case report and review of literature. *Radiology* 1999;213:773–6.
- Pattee PL, Johns PC, Chambers RJ. Radiation risk to patients from percutaneous transluminal coronary angioplasty. *J Am Coll Cardiol* 1993;22:1044–51.
- Cascade PN, Peterson LE, Wajszczuk WJ, Mantel J. Radiation exposure to patients undergoing percutaneous transluminal coronary angioplasty. *Am J Cardiol* 1987;59:996–7.
- Meier B. Radiation exposure in the cardiac catheterization laboratory: an issue or a non-issue. *Cathet Cardiovasc Diagn* 1997;40:352.
- Federman J, Bell MR, Wondrow MA, Grill DE, Holmes DR. Does the use of new intracoronary interventional devices prolong radiation exposure in the cardiac catheterization laboratory? *J Am Coll Cardiol* 1994;23:347–51.
- Wagner LK, Eifel PJ, Geise RA. Potential biological effects following high x-ray dose interventional procedures. *J Vasc Interv Radiol* 1994;5:71–84.
- Martin CJ. Measurement of patient entrance surface dose rates for fluoroscopic x-ray units. *Phys Med Biol* 1995;40:823–4.
- McParland BJ. Entrance skin dose estimates derived from dose–area product measurements in interventional radiological procedures. *Br J Radiol* 1998;71:1288–95.
- Betsou S, Efstathiopoulos EF, Katritsis D, Faulkner K, Panayiotakis G. Patient radiation doses during cardiac catheterization procedures. *Br J Radiol* 1998;71:634–9.
- Zorzetto M, Bernardi G, Morocutti G, Fontanelli A. Radiation exposure to patients and operators during diagnostic catheterization and coronary angioplasty. *Cathet Cardiovasc Diagn* 1997;40:348–51.
- Vañó E, González L, Guibelalde E, Fernández JM, Ten JI. Radiation exposure of medical staff in interventional and cardiac radiology. *Br J Radiol* 1998;71:954–60.
- Benson JS. Patient and physician radiation exposure during fluoroscopy. *Radiology* 1992;182:286.
- Stern SH, Rosenstein M, Renaud L, Zankl M. Handbook of selected tissue doses for fluoroscopic and cineangiographic examination of coronary arteries. HHS Publication FDA 95-8289. Rockville, MD: US Department of Health and Human Services, 1995.
- LeHeron JC. Estimation of effective dose to the patient during medical x-ray examinations from measurements of dose–area product. *Phys Med Biol* 1992;37:2117–26.
- Karppinen J, Parviainen T, Servomaa A, Komppa T. Radiation risk and exposure of radiologists and patients during coronary angiography and percutaneous transluminal coronary angioplasty (PTCA). *Radiat Prot Dosim* 1995;57:481–5.
- Pratt TA, Shaw AJ. Factors affecting the radiation dose to the lens of the eye during cardiac catheterization procedures. *Br J Radiol* 1993;66:346–50.
- Vañó E, González L, Fernández JM, Guibelalde E. Patient dose values in interventional radiology. *Br J Radiol* 1995;68:1215–20.
- Ten JI, Vañó E, Fernández JM, Guibelalde E. CARDIDOSE ver 1.0 software for estimating effective and organ dose in interventional cardiology. Madrid: Medical Physics Group, Radiology Department, Complutense University, 1998.
- International Commission on Radiological Protection. Radiological protection and safety in medicine, ICRP Publication 73. Ann ICRP 1996; 26(2).
- Geise RA, Ansel HJ. Radiotherapy verification film for estimating cumulative entrance skin exposure for fluoroscopic examinations. *Health Phys* 1990; 59:295–8.
- Fajardo LC, Geise RA, Ritenoure RA. A survey of film for use as a dosimeter in interventional radiology. *Health Phys* 1995;68:595–9.
- Vañó E, Guibelalde E, Fernández JM, González L, Ten JI. Patient dosimetry in interventional radiology using slow film systems. *Br J Radiol* 1997;70:195–200.
- US Food & Drug Administration (FDA). Avoidance of serious x-ray induced skin injuries to patients during fluoroscopically-guided procedures. Medical Bulletin 1994;24(2):7–17.
- Joint WHO/ISH/CE workshop on efficacy and radiation safety in interventional radiology; 1995 October 9–13; Munich–Neuherberg, Germany. Germany: Bundesamt für Strahlenschutz, BfS-ISH-178/97, 1997.
- Anderson JA, Wang J, Clarke GD. Management of radiation exposures in the cardiac catheterization laboratories. In: RSNA categorical course in diagnostic radiology physics: cardiac catheterization imaging. RSNA; 1998:211–22.
- Wagner LK, Archer BR, Cohen AM. Management of patient skin dose in fluoroscopically guided interventional procedures. *J Vasc Interv Radiol* 2000;11:25–33.
- Braunlich PF. Laser heated thermoluminescence dosimetry. In: Rao RP, editor. Luminiscence: phenomena, materials and devices. Cormack, NY: Nova Science Publishers, Inc., 1992.
- Geise RA. Clinical dose monitoring. In: RSNA categorical course in diagnostic radiology physics: cardiac catheterization imaging. RSNA 1998: 241–7.
- Geise RA, Schueler BA, Lien W, Jones SC. Suitability of laser stimulated TLD arrays as patient dose monitors in high dose x-ray imaging. *Med Phys* 1997;24:1643–6.
- Gknatsios NA, Huda W, Peters KR, Freeman JA. Evaluation of an on-line patient exposure meter in neuroradiology. *Radiology* 1997;203:837–42.

32. Clinical Microsystems, Inc, Biomedical Instrumentation, Arlington, VA (USA). Patient Exposure Management Network (PEMNET). Pamphlet distributed to the attendants to the 1998 Radiological Society of North America Conference; 1998 November 29–December 4; Chicago, IL.
33. Pina MV, Deye JA. Comparison of two patient exposure measuring devices in a busy cardiac catheterization laboratory. *Med Phys* 1993;20:917.
34. Gfirtner H, Stieve FE, Wild J. A new Diamentor for measuring kerma-area product and air-kerma simultaneously. *Med Phys* 1997;24:655–64.
35. Ad den Boer BS, De Feyter PJ, Hummel WA, Keane D, Roelandt JRTC. Reduction of radiation exposure while maintaining high quality fluoroscopic images during interventional cardiology using novel x-ray tube technology with extrabeam filtering. *Circulation* 1994;89:2710–4.
36. Archer BR, Wagner LK. Protecting patients by training physicians in fluoroscopic radiation management. *J Appl Clin Med Phys* 2000;1:1–6.
37. European Commission. Radiation protection in interventional radiology, ERPET course. Proceedings published in 1998 by the European Commission (Ref. XII-237-98).
38. Wagner LK, Archer BR. Minimizing risks from fluoroscopy x-rays. A credentialing program for anesthesiologists, cardiologists, gastroenterologists, interventionalists, orthopedists, pulmonologists, radiologists, surgeons and urologists. Radiation Management Partnership 1998, 2nd edition, The Woodlands, TX 77381, USA.
39. Malone JF. Standards for interventional radiology equipment. In: Balter S, editor. Physical and technical aspects of angiography and interventional radiology. A categorical course in physics; Annual Meeting of the Radiological Society of North America. Chicago, IL: RSNA, 1995:207–12.
40. Geise RA, O'Dea TJ. Radiation dose in interventional fluoroscopic procedures. *Appl Radiat Isot* 1999;50:173–84.
41. Cusma JT, Malcolm RB, Wondrow MA, Taubel JP, Holmes DR. Real-time measurement of radiation exposure to patients during diagnostic coronary angiography and percutaneous interventional procedures. *J Am Coll Cardiol* 1999;33:427–35.
42. European Commission. Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure and repealing Directive 84/466 Euratom. *Official Journal of the European Communities* 1997;L 180:22–7.
43. BOE 1999. Royal Decree 1976/1999, from the Health and Consumer Affairs Department, establishing quality criteria in radiodiagnostics. In: State Official Bulletin of December 29 1999: 45891:45900. (In Spanish.)
44. European Commission. Guidance on diagnostic reference levels (DRLs) for medical exposures. Radiation Protection 109, Directorate-General Environment, Nuclear Safety and Civil Protection, 1999.
45. Vañó E, Arranz L, Sastre JM, Moro C, Ledo A, Garate MT, et al. Dosimetric and radiation protection considerations based on some cases of patient skin injuries in interventional cardiology. *Br J Radiol* 1998;71:510–6.

14.- Trabajo VII

INCREASES IN PATIENT DOSES NEED TO BE AVOIDED WHEN UPGRADING INTERVENTIONAL CARDIOLOGY SYSTEMS TO FLAT DETECTORS

C. Prieto^{1,*}, E. Vano^{1,2}, J. M. Fernández^{1,2}, D. Martínez¹ and R. Sánchez¹

¹Medical Physics Service San Carlos University Hospital, 28040 Madrid, Spain

²Radiology Department, Medicine School, Complutense University, 28040 Madrid, Spain

*Corresponding author: cprieto.hcsc@gmail.com

The aim of this study was to evaluate patient doses in two interventional cardiology laboratories over a period of 1 y in which the imaging devices were changed from image intensifier (II) to flat detector (FD). Dosimetric data from a total of 1040 coronary angiography (CA) procedures and 1087 percutaneous transluminal coronary angioplasty (PTCA) procedures were gathered. During the period studied with II imaging, median values of dose area product were 28 Gy cm² for CA and 57 Gy cm² for PTCA. In the first half of the year with FD imaging, median values were 37 Gy cm² for CA and 89 Gy cm² for PTCA. A significant increase in patient doses was noticed in the early stages of use of FD technology for imaging IC procedures, while fluoroscopy time and number of images remained similar. A careful setting of the X-ray systems, after upgrading the imaging system, is essential to avoid unjustified increases in patient doses.

INTRODUCTION

The new digital systems present advantages⁽¹⁾ (lack of geometric distortion, excellent coarse contrast, large dynamic range, high X-ray sensitivity and advanced image processing) over the conventional systems. These advantages should facilitate interventional cardiology (IC) procedures and theoretically give the opportunity to optimise the technique in terms of radiation dose⁽²⁾.

Complex IC procedures are high-dose procedures for both patients and staff, resulting, on some occasions, in deterministic effects (skin injuries) due to the high radiation doses imparted to some regions of the patient skin^(3–5). Percutaneous transluminal coronary angioplasty (PTCA) is one of the most frequent interventional procedures in cardiology and one which sometimes requires long fluoroscopy time and a large number of cine frames to evaluate and quantify the patient lesion and the result of the treatment. Therefore, the estimation of patient doses and its evolution in interventional procedures is a key aspect in every quality assurance (QA) programme.

In this work, patient doses were analysed along a period of 1 y in which the imaging devices of two IC laboratories were changed from image intensifier (II) to flat detector (FD).

MATERIALS AND METHODS

From March 2009 to March 2010, patient dose measurements from 1040 patients who underwent coronary angiography (CA) procedures on the one hand and from 1085 patients that had PTCA on

the other hand were gathered. The procedures were carried out in two dedicated X-ray interventional cardiology rooms by senior cardiologists or fellows, under the supervision of senior specialists. During the year-long evaluation, all the professionals performing these procedures had very similar profiles and the procedures performed during this period can be considered of similar level of complexity.

The X-ray systems were used under a QA programme, including periodic constancy checks to evaluate the dose rate at the entrance of the image receptor and at the entrance of different thicknesses of polymethyl methacrylate (PMMA) and copper, following the protocol proposed by the European DIMOND consortium⁽⁶⁾. The two X-ray systems underwent periodic imaging performance measurements and quality control and conformed to the manufacturer's specifications as well as to the reference baselines of the acceptance tests.

The dose area product (DAP) values, together with the fluoroscopy time (FT) and the total number of cine frames (NF) were recorded. The data from 698 CA procedures were recorded along with 376 PTCA procedures performed 6 months before the update of both Philips Integris H5000 X-ray systems with II to Philips Allura XPER FD10 with FD (update realised in September 2009). The same data were recorded for 342 CA and 709 PTCA procedures in the first 6-month period of use of the FD systems. Given that staff, complexity and working procedures remained basically the same, any change in patient doses could only be attributed to the change in the settings and user protocols of the fluoroscopy and cine modes.

The DAP was measured with the built-in calibrated ionisation transmission chambers (PTW, Freiburg, Germany).

RESULTS

Tables 1 and 2 compare DAP, FT and NF in CA and PTCA procedures 6 months before and after the update of the X-ray system.

Since the DAP values measured did not exhibit a normal distribution (see Figure 1), the range, median and third quartile values were used to characterise the patient dose distributions. As expected, PTCA presented higher median values of DAP, FT and NF than that of CA. In most of the cases, PTCA procedures were considered the typical 'interventional procedure', with a diagnostic part followed by the angioplasty. In the first period considered (with II imaging), median DAP was 28 Gy cm² for CA and 57 Gy cm² for PTCA. In the first 6 months of use of FD, imaging median values were 37 Gy cm² for CA and 89 Gy cm² for PTCA.

Figures 1 and 2 show the frequency histogram of DAP for CA and PTCA procedures in the 6-month period before (II) and after (FD) the upgrade of the X-ray system. Differences of distributions for II and FD are statistically significant ($p < 0.001$, Mann–Whitney U -test).

DISCUSSION AND CONCLUSIONS

Before the update of the X-ray system, the median values of DAP were lower than those proposed by the European diagnostic reference levels for interventional cardiology, i.e. 45 Gy cm² for CA⁽⁷⁾ and 75 or

Table 2. DAP, fluoro time and number of frames for PTCA, 6 months before and after the update of the X-ray device.

PTCA procedures	DAP (Gy cm ²)	Fluoro time (m)	Number of frames
6 months before (II)			
Number	376	190	376
Minimum	10.0	3.4	343
Maximum	226.2	110.2	4064
Mean	65.7	23.7	1297
Median	57.0	19.2	1219
Third quartile	78.5	27.3	1543
6 months after (FD)			
Number	709	710	713
Minimum	28.5	2.3	37
Maximum	492.1	161.2	5533
Mean	112.6	20.2	1476
Median	89.4	17.1	1313
Third quartile	135.3	25.5	1734

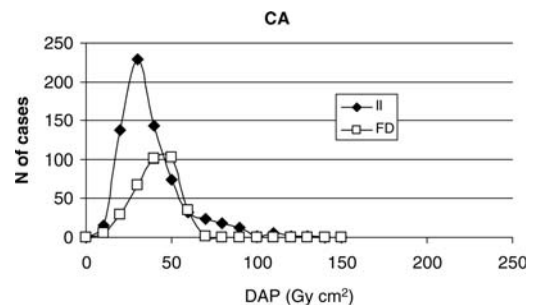


Figure 1. Distribution (frequency histogram) of DAP for CA procedures in the 6-month period before (II) and after (FD) the upgrade of the equipment.

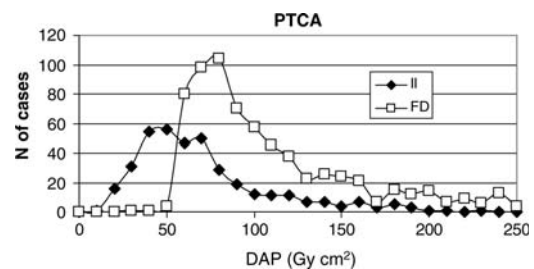


Figure 2. Distribution (frequency histogram) of DAP for percutaneous transluminal coronary angioplasty procedures in the 6-month period before (II) and after (FD) the upgrade of the equipment.

85 Gy cm² for PTCA^(7, 8). Nevertheless, from the results obtained, it is clear that the update of the X-ray system has implied a higher median DAP (32 %

Table 1. DAP, fluoro time and number of frames for CA, 6 months before and after the update of the X-ray device.

CA procedures	DAP (Gy cm ²)	Fluoro time (m)	Number of frames
6 months before (II)			
Number	698	372	697
Minimum	1.6	1.1	34
Maximum	322.3	61.1	2545
Mean	33.7	11.4	843
Median	28.2	8.2	820
Third quartile	39.5	13.4	957
6 months after (FD)			
Number	342	342	342
Minimum	5.7	0.5	88
Maximum	65.8	46.4	1895
Mean	35.8	7.6	790
Median	37.2	6.4	782
Third quartile	44.9	10.2	961

for CA and 57 % for PTCA). As staff and complexity of the procedures have remained basically the same, only minor changes in FT (−1.3 min for CA and 2.1 min for PTCA) and NF (−5 % for CA and 8 % for PTCA) were found. The median value of the DAP for PTCA has increased to 89 Gy cm², which is slightly above the proposed diagnostic reference levels for this kind of procedure.

Therefore, during the first period using the FD technology, the theoretical benefits reported in the literature^(refs 9, 10) on patient doses were not evident in the centre here. On the contrary, a significant increase of DAP values (with no change in FT and NF) suggested that the setting of the X-ray system needed to be improved. Some authors^(11, 12) have reported no changes in patient doses in the transition to FD, while others⁽¹³⁾ have found an increase in patient doses similar to those of this study. When higher patient doses are found after the FD upgrade, both clinical protocols and the setting of the X-ray system should be optimised⁽¹⁴⁾.

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REFERENCES

1. Spahn, M. *Flat detectors and their clinical applications*. Eur. Radiol. **15**(9), 1934–1947 (2005).
2. Tsapaki, V., Kottou, S., Kollaros, N., Dafnomili, P., Koutelou, M., Vano, E. and Neofotistou, V. *Comparison of a conventional and a flat-panel digital system in interventional cardiology procedures*. Br. J. Radiol. **77**(919), 562–567 (2004).
3. International Commission on Radiological Protection. *Avoidance of radiation injuries from medical interventional procedures*. ICRP Publication 85. Ann. ICRP **30**(7) (2000).
4. Koenig, T. R., Mettler, F. A. and Wagner, L. K. *Skin injuries from fluoroscopically guided procedures: Part 2, Review of 73 cases and recommendations for minimizing dose delivered to patient*. AJR **177**, 13–20 (2001).
5. Vano, E., Arranz, L., Sastre, J. M., Moro, C., Ledo, A., Garate, M. T. and Minguez, I. *Dosimetric and radiation protection considerations based on same cases of patient skin injuries in interventional cardiology*. Br. J. Radiol. **71**, 510–516 (1998).
6. Faulkner, K. *Introduction to constancy check protocols in fluoroscopic systems*. Radiat. Prot. Dosim. **94**(1–2), 65–68 (2001).
7. Neofotistou, V. *et al.* *Preliminary reference levels in interventional cardiology*. Eur. Radiol. **13**(10), 2259–2263 (2003).
8. Padovani, R. *et al.* *Reference levels at European level for cardiac interventional procedures*. Radiat. Prot. Dosim. **119**, 104–107 (2008).
9. Mesbahi, A., Mehnati, P., Keshtkar, A. and Aslanabadi, N. *Comparison of radiation dose to patient and staff for two interventional cardiology units: a phantom study*. Radiat. Prot. Dosim. **131**, 399–403 (2008).
10. Bokou, C., Schreiner-Karoussou, A., Breisch, R. and Beissel, J. *Changing from image intensifier to flat detector technology for interventional cardiology procedures: a practical point of view*. Radiat. Prot. Dosim. **129**, 83–86 (2008).
11. Bogaert, E., Bacher, K., Lapere, R. and Thierens, H. *Does digital flat detector technology tip the scale towards better image quality or reduced patient dose in interventional cardiology?* Eur. J. Radiol. **72**, 348–353 (2008).
12. Davies, A., Cowen, A., Kengyelics, S., Moore, J. and Sivananthan, M. *Do flat detector cardiac X-ray systems convey advantages over image-intensifier based systems? Study comparing X-ray dose and image quality*. Eur. Radiol. **17**, 1787–1794 (2007).
13. Trianni, G. and Padovani, R. *Are new technologies always reducing patient doses in cardiac procedures?* Radiat. Prot. Dosim. **117**, 97–101 (2005).
14. Simon, R., Vano, E., Prieto, C., Fernandez, J. M., Ordiales, J. M. and Martinez, D. *Criteria to optimise a dynamic flat detector system used for interventional radiology*. Radiat. Prot. Dosim. **129**, 261–264 (2008).

15.- Trabajo VIII

AUTOMATIC MANAGEMENT SYSTEM FOR DOSE PARAMETERS IN INTERVENTIONAL RADIOLOGY AND CARDIOLOGY

J. I. Ten^{1,2,*}, J. M. Fernandez^{2,3} and E. Vaño^{2,3}

¹Radiology Department, San Carlos University Hospital, Madrid 28040, Spain

²Radiology Department, Complutense University, Madrid 28040, Spain

³Medical Physics Service, San Carlos University Hospital, Madrid 28040, Spain

*Corresponding author: jten.hcsc@salud.madrid.org

The purpose of this work was to develop an automatic management system to archive and analyse the major study parameters and patient doses for fluoroscopy guided procedures performed in cardiology and interventional radiology systems. The X-ray systems used for this trial have the capability to export at the end of the procedure and via e-mail the technical parameters of the study and the patient dose values. An application was developed to query and retrieve from a mail server, all study reports sent by the imaging modality and store them on a Microsoft SQL Server data base. The results from 3538 interventional study reports generated by 7 interventional systems were processed. In the case of some technical parameters and patient doses, alarms were added to receive malfunction alerts so as to immediately take appropriate corrective actions.

INTRODUCTION

The International Commission on Radiological Protection (ICRP) has identified interventional radiology and cardiology as practices needing a robust radiation protection (RP) programme^(1–3) and recommended the use of diagnostic reference levels (DRLs) in fluoroscopy guided procedures. The European Directive 97/43/Euratom and the draft for the new European Basic Safety Standards (BSS) require that patient doses be measured, registered and transferred to the clinical records (this last requirement was introduced in the draft of the new BSS). There have been many efforts in the radiology industry and standardisation organisations in the last few years to fulfill these requirements.

Apart from the legal requirements, radiologists, cardiologists and medical physicists need to know the radiation exposure parameters and the resulting patient doses to help in the optimisation process. This knowledge allows to draw comparisons with the DRLs and to initiate corrective actions when, for some kind of procedures, patient doses exceed the DRLs.

Skin radiation injuries on patients have been reported^(4–8) in a significant number of cases and the clinical follow-up of the patients receiving high radiation doses needs to be considered. Moreover, as the complexity of some interventional procedures and of minimally invasive therapies is increasing, so is the percentage of patients receiving high radiation doses.

In many interventional radiology and cardiology services, the number of catheterisation laboratories and procedures carried out daily can be quite high (3–6 laboratories and 20–40 procedures per day). It

seems thus convenient to create an automatic system receiving and processing the main radiographic, geometric and patient dose parameters in real time to act in accordance with the RP programme.

The purpose of this work was to develop an automatic management system to archive and to analyse the study of the main parameters and patient dose values for interventional procedures in cardiology and interventional radiology in a big university hospital and then offer the experience to other institutions.

MATERIALS AND METHODS

The automatic system called ‘Dose on line for Interventional Radiology’ (DOLIR) is the continuation of a previous work developed by the Medical Physics Group at the San Carlos University Hospital during the European Research Actions DIMOND and SENTINEL^(9, 10). The system is to be considered as an ‘interim’ solution until the DICOM dose-structured reports⁽¹¹⁾ (DSR) are available. From previous experience with similar standards, 3–5 y may be necessary for the industry and the users to implement the new DSR. In addition, DOLIR includes several features that could also be used with the future DICOM DSR.

DOLIR was implemented with the interventional radiology and cardiology Philips X-ray systems of the hospital, using the patient dose reports developed by this company.

The X-ray systems used for this trial were the following: one Allura FD-20 (dedicated to general peripheral interventional radiology), one biplane Allura FD-20/FD-10 (dedicated to interventional

neuroradiology) and five Allura FD-10 (four dedicated to interventional cardiology and one to cardiac electrophysiology).

All these X-ray systems have the capability to export at the end of an interventional procedure and via e-mail, a patient dose report including series, study and patient information. A commercial mail server was installed on the intranet site to receive e-mail messages from all the X-ray systems. An application with POP3 client connectivity was developed to query and retrieve all the study reports from the mail server and store them on a Microsoft SQL Server data base.

Individual trigger levels or alarms for potential clinical follow-up

A set of alarms was defined to alert the medical physics service in case any relevant event would occur. For patient doses, two kinds of alarms were activated: one for high doses in individual patients (for a potential clinical follow-up if skin doses were >3 Gy) and the other one, for the median values from the last 30 procedures (in case they would be higher than the DRLs for such procedures).

Furthermore, trigger levels were agreed upon for relevant individual parameters or for a group of procedures (e.g. procedures carried out on patients under 40 y of age, or patients undergoing repeated procedures within 60 d, or large distances between the patient and the image detector, or similar multiple angulations in several cine or DSA series, etc.).

The classical patient dose parameters were included for the alarms as follows:

- (1) dose or kerma area product (DAP),
- (2) cumulative air kerma at the interventional reference point (roughly similar to the cumulative patient skin dose),
- (3) fluoroscopy time and number of acquired images.
- (4) peak skin dose (related to the C-arm angulations and the fluoroscopy runs and number of images in the different series).

These values allow to select automatically a subgroup of patients and to later decide on a potential follow-up. Initially, the alarms for individual procedures were set when measured values resulted in a factor of 2 or higher than the DRLs.

Philips systems have recently introduced a new feature in their patient dose reports that takes into account the different C-arm angulations and the level of exposure in these angulations when estimating the patient skin dose distribution. The reported values are expressed as percentages of skin dose for the different angulations (each corresponding to a different skin region irradiated). In a specific angulation, 100 % means that the patient skin has received

around 2 Gy. For this parameter, the value of 200 % as individual alarm was selected to include the patient in a potential clinical follow-up.

Alarms to detect changes in tendency

Alarms (including the ones already set for individual patients) were programmed for the last 30 procedures, when the median values result higher than the DRLs. The parameters contained in the patient dose reports and related to the optimisation of the procedures as median values included were as follows:

- (1) DAP.
- (2) Cumulative air kerma at the interventional reference point (roughly similar to the cumulative patient skin dose).
- (3) Fluoroscopy time.
- (4) Total number of images acquired (partly reflecting the complexity of the procedure, but also reflecting the practitioners' lack of awareness if this number is >1500 in cardiology, >100 in peripheral procedures and >500 in neuroradiology).
- (5) Peak skin dose.
- (6) Number of series per procedure (representative of a certain complexity of the procedure).
- (7) Number of frames per series (partly reflecting the complexity of the procedure, but also reflecting the practitioners' lack of awareness if this mean number is >60 in cardiology, >10 in peripheral procedures and >30 in neuroradiology).
- (8) Difference between total number of images and number of 'radiographic images' (in this group: the cine and DSA images). It is considered good practice to archive fluoroscopy runs to a level of >30 %.
- (9) Number of pulses or images/s. If, in cardiology, the number of images used exceeds 15 images/s in >20 % of the series, a corrective action is suggested. As for peripheral or neuroradiology, that number is >3 images/s in >40 % of the series.
- (10) Distance focus-image (DFI) detector. Situations where DFI is >110 cm for >30 % of the series are considered for alarm.

In any case, the initial values of the trigger levels and alarms will need to be refined so as to select only a reasonable number of events worth corrective actions.

With this system, it is also possible to do a statistical analysis of the main parameters and then compare the different catheterisation laboratories, procedures or specialists doing the procedures (e.g. senior versus residents).

Table 1. Study DAP (Gy cm²), fluoroscopy time (s) and total number of values acquired images since December 2009.

Laboratory	Median	Mean	Maximum	Minimum	Std Dev	Third quartile
Cardio 1 (229)						
DAP	29	38	811	0.1	62	59
Fluoro time	*	*	*	*	*	*
Frames	76	81	5170	0	81	123
Cardio 3 (797)						
DAP	86	102	764	0.3	74	136
Fluoro time	780	970	5893	31	970	1204
Frames	1237	1246	5533	0	1246	1316
Cardio 4 (738)						
DAP	79	101	646	6.5	79	128
Fluoro time	988	1040	5964	61	1053	1132
Frames	1056	1224	3564	0	1224	1423
Cardio 5 (408)						
DAP	68	82	305	12.7	46	101
Fluoro time	531	666	2662	0	666	743
Frames	897	1034	2551	205	1034	1290
Cardio 6 (413)						
DAP	54	65	342	5.6	40	83
Fluoro time	602	665	2877	89	656	792
Frames	879	956	2892	24	956	974
Neuro (332)						
DAP	123	165	1405	0.7	188	121
Fluoro time	1023	1138	10 599	7	1138	1320
Frames	503	525	2663	0	525	625
Vascular (621)						
DAP	57	82	754	0.3	110	232
Fluoro time	396	489	4665	5	489	512
Frames	46	58	383	0	58	74

RESULTS

Patient demographic data were collected from the email headers sent by the X-ray systems from the body of messages containing fluoroscopy time, fluoroscopy DAP, exposure DAP (for cine or DSA images), cumulative DAP for the full study, cumulative air kerma at the interventional reference point (frontal and lateral C-arms when present) and total number of frames (split in radiographic and fluoroscopy, when these runs had been archived) were collected at a study level, while series time, frames per second, kilovoltage potential, milliamperage exposure time, projection angles, focus–detector distance and total frames were stored on the series level.

To this day, 3538 interventional study reports generated in accordance with these modalities have been received at the mail server and processed since December 2009. Table 1 shows the study DAP (Gy cm²), the fluoroscopy time (s) and the total number of acquired images for every X-ray system in this period.

The triggers set in the system have detected a total of 2346 (66 %) studies including one or more alarms at patient, study or series level. Seven hundred and sixty-eight (22 %) studies received more than two

alarms at the patient-study level (e.g. patient with previous studies in the last 60 d, number of series per study higher than the reference value, DFI > 110 cm for >30 % of the series, etc.) and were potentially eligible for individual analysis to establish a clinical follow-up and detect possible occurrence of skin injuries. The most frequent alarms are the following: 1598 (45 %) studies in which DFI is >110 cm for >30 % of the series, 1331 (37 %) studies with high number of frames per series, 943 (27 %) studies with number of frames per study higher than the reference value for the room, 770 (22 %) studies with more than 20 series per study, 338 (10 %) patients with previous studies in the last 60 d, 151 (4 %) patients under 40 y of age, 62 (2 %) studies with fluoroscopy time above 90 min and 25 (1 %) studies in which the patient skin has received about 4 Gy on the same area. Further experiences will be necessary to refine these trigger levels and select the most relevant ones for the best protection of the patients.

CONCLUSIONS

The system presented allows an automatic processing of the parameters related to patient doses in

interventional systems. It also allows the detection of doses higher than the trigger levels for potential clinical follow-up and deviations in tendency when median values result higher than the DRLs. The analysis of the different series of acquisitions and other radiographic and geometrical parameters may help in the optimisation of the procedures. Because of the high complexity of specific procedures (e.g. total occlusions in cardiology) the alarm levels need to be increased under certain circumstances.

However, serious limitations were confronted in the analysis of the results and that, mainly because of the routine workflow: manual action of the operator is unfortunately still required to send the dose report to the mail server when the procedures are over. On the one hand, operators sometimes forget to send the reports and then the dose data are lost. On the other hand, the reports of many examinations do not bear the physician's identification and the procedure description. What is more is that the medical specialists have not standardised the names of the procedures and consequently an additional manual action is then required that is not always done.

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REFERENCES

1. European Commission. *Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure*. Off. J. Eur. Commun. L. 180:22–27; 9th July 1997. Available on http://ec.europa.eu/energy/nuclear/radioprotection/doc/legislation/9743_en.pdf.
2. ICRP. *Radiological protection in medicine*. Publication 105. Ann. ICRP **37**(6), pp. 1–63 (2008).
3. *The 2007 recommendations of the International Commission on Radiological Protection*. Publication 103. Ann. ICRP **37**(2–4), pp. 1–332 (2007).
4. ICRP. *Avoidance of radiation injuries from medical interventional procedures*. ICRP Publication 85. Ann. ICRP **30**(2), pp. 1–67 (2000).
5. Koenig, T. R., Wolff, D., Mettler, F. A. and Wagner, L. K. *Skin injuries from fluoroscopically guided procedures: Part 1 Characteristics of radiation injury*. Am. J. Roentgenol. **177**(1), 3–11 (2001).
6. Koenig, T. R., Mettler, F. A. and Wagner, L. K. *Skin injuries from fluoroscopically guided procedures: Part Review of 73 cases and recommendations for minimizing dose delivered to patient*. Am. J. Roentgenol. **177**(1), 13–20 (2001).
7. Vano, E., Arranz, L., Sastre, J. M., Moro, C., Ledo, A., Garate, M. T. and Minguez, I. *Dosimetric and radiation protection considerations based on same cases of patient skin injuries in interventional cardiology*. Br. J. Radiol. **71**, 510–516 (1998).
8. Vano, E., Goicolea, J., Galvan, C., Gonzalez, L., Meiggs, L., Ten, J. I. and Macaya, C. *Skin radiation injuries in patients following repeated coronary angioplasty procedures*. Br. J. Radiol. **74**(887), 1023–1031 (2001).
9. Faulkner, K. *The DIMOND project and its impact on radiation protection*. Radiat. Prot. Dosim. **117**(1–3), 3–6 (2005).
10. Faulkner, K., Malone, J., Vano, E., Padovani, R., Busch, H. P., Zoetelief, J. H. and Bosmans, H. *The SENTINEL project*. Radiat. Prot. Dosim. **129**(1–3), 3–5 (2008).
11. Digital Imaging and Communications in Medicine (DICOM). *Supplement 150: Radiation dose related information in radiology reports*. Available on <http://medical.nema.org/>.

